

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 - - -

16 May 10, 2019

17 - - -

18 Videotaped deposition of
19 PATRICK KELLY, taken pursuant to notice,
20 was held at the offices of Baron & Budd,
21 600 New Hampshire Avenue, NW, Washington,
22 D.C., beginning at 8:58 a.m., on the
23 above date, before Michelle L. Gray, a
24 Registered Professional Reporter,
 Certified Shorthand Reporter, Certified
 Realtime Reporter, and Notary Public.

 - - -

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9 James Beall

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2 I N D E X
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Testimony of:

PATRICK KELLY

By Mr. Pifko 26

By Ms. MacKay 438

11 - - -
12 E X H I B I T S
13 - - -

NO.	DESCRIPTION	PAGE
HDA Kelly-1	Second Amended Notice of Subpoena For Deposition	32
HDA Kelly-2	E-mail, 10/31/16 Subject, Chronology Of HDMA DEA Involvement Updated 10/31/16 & Attachment HDA_MDL_000081363-76	35

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-3	E-mail Thread	50
8		5/30/07	
9		Subject, Confirmed	
10		HDMA Conference Call	
11		On DEA Issues	
12		His-MDL-00620224-29	
13	HDA		
14	Kelly-4	E-mail Thread	59
15		9/26/07	
16		Subject, HDMA DEA	
17		Strategy Meeting	
18		Availability	
19		CAH_MDL_PRIORPROD_DEA07	
20		00877471-73	
21	HDA		
22	Kelly-5	E-mail Thread	66
23		10/30/07	
24		Subject, HDMA Board	
25		Meeting	
26		HDA_MDL_000213427	
27	HDA		
28	Kelly-6	PowerPoint	72
29		Slides for Packaging	
30		Call 12/10/07	
31		HDA_MDL_000143030	
32	HDA		
33	Kelly-7	Letter, 7/25/07	79
34		To Rannazzisi	
35		CAH_MDL2804_02489197-98	
36			
37			
38			
39			
40			
41			
42			
43			
44			
45			
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47			
48			
49			
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1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-8	E-mail Thread	81
8		10/28/11	
9		Subject, DEA Question	
10		CAH_MDL2804_02489160	
11	HDA		
12	Kelly-9	Summary of the DEA	84
13		HDMA Meeting on	
14		Suspicious Orders	
15		Meeting Date	
16		9/7/07	
17		CAH_MDL2804_02489199-200	
18	HDA		
19	Kelly-10	E-mail Thread	91
20		1/2/08	
21		Subject, Suspicious	
22		Orders Project	
23		HDA_MDL_000151104-19	
24			
25	HDA		
26	Kelly-11	NWDA Suspicious	108
27		Order Monitoring	
28		System	
29		CAH_MDL2804_02201910-16	
30	HDA		
31	Kelly-12	E-mail Thread	119
32		1/10/08	
33		Subject, Suspicious	
34		Orders Business Procedures	
35		HDA_MDL_000150198	
36			
37			
38			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-13	E-mail Thread	122
8		1/17/08	
9		Subject, Rewrite	
10		HDA_MDL_000139414-15	
11	HDA		
12	Kelly-14	E-mail Thread	131
13		2/6/08	
14		Subject, HDMA RAC	
15		Conference Call	
16		Reminder	
17		HDA_MDL_000213181-82	
18	HDA		
19	Kelly-15	Slide Deck	136
20		1/31/08	
21		Review Anti-Trust	
22		And Anti-Harassment	
23		Policies	
24		HDA_MDL_000213212-28	
25	HDA		
26	Kelly-16	Slide Deck	151
27		Suspicious Orders	
28		and Diversion	
29		Prevention	
30		HDMA, 1/31/08	
31		Arlington VA	
32		HDA_MDL_000213229-40	
33	HDA		
34	Kelly-17	E-mail, 2/5/08	160
35		Subject, Follow-up	
36		HDA_MDL_000141125-33	

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-18	E-mail, 2/6/08 Subject, Discussion Intro HDA_MDL_000217851-53	181
8			
9	HDA		
10	Kelly-19	E-mail Thread 2/6/08 Subject, HDMA RAC Conference Call Reminder HDA_MDL_000148603-33	186
11			
12			
13	HDA		
14	Kelly-20	HDMA DEA Suspicious Orders Best Practices GPPC 2/12/08 HDA_MDL_000213058-77	199
15			
16			
17	HDA		
18	Kelly-21	E-mail Thread 3/4/08 Subject, HDMA RAC Conference Call Reminder CAH_MDL2804_01521412-69	210
19			
20	HDA		
21	Kelly-22	E-mail Thread 3/20/08 Subject, DEA Strategy Document and FDA Update Anda_Opioids_MDL_ 0000157358-73	215
22			
23			
24			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-23	Draft Summary of the DEA-HDMA Meeting 4/15/08 CAH_MDL2804_ 02489188-90	231
8			
9	HDA		
10	Kelly-24	E-mail Thread 1/7/08 Subject, RAC Vice Chairmanship HDA_MDL_000156499-01	242
11			
12	HDA		
13	Kelly-25	DEA Suspicious Orders: Recommended Industry Compliance Guidelines Regional Roundtable 5/7/08 HDA_MDL_000213078-88	261
14			
15	HDA		
16	Kelly-26	DRAFT DEA Comments From the 6/4/08 Meeting on Suspicious Orders CAH_MDL2804_02489191-96	263
17			
18	HDA		
19	Kelly-27	HDMA Industry Compliance Guidelines HDS_MDL_00218651-65	283
20			
21			
22			
23			
24			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-28	Letter, 10/17/08 To Gray from Goggin CAH_MDL2804_02489203	284
8			
9	HDA		
10	Kelly-29	Slide Deck Webinar Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion Of Controlled Substances 11/14/08 HDA_MDL_000145918-69	287
11			
12			
13	HDA		
14	Kelly-30	E-mail Thread 6/12/13 Subject, For Review RX Drug Abuse/Diversion One Pager HDA_MDL_000080421-24	294
15			
16			
17	HDA		
18	Kelly-31	Chronology of HDMA/DEA Executive Committee and Board of Directors' Drug Abuse 1/2/18 HDA_MDL_000155930-47	299
19			
20			
21			
22			
23			
24			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-32	E-mail Thread	302
		10/1/13	
		Subject, HDMA - Review	
8		Requested by Thursday	
		10/3 12 Noon Eastern	
9		HDA_MDL_000081415-16	
10	HDA		
	Kelly-33	GAO Meeting on DEA	303
11		Draft TPs 9/20/10	
		HDA_MDL_000139905-10	
12			
	HDA		
13	Kelly-34	E-mail Thread	314
		4/20/12	
14		Subject, DEA	
		Initiatives	
15		HDA_MDL_000215234-36	
16	HDA		
	Kelly-35	E-mail Thread	331
17		12/19/13	
		Subject, Follow-up	
18		HDMA Drug Diversion	
		Task Force	
19		Meeting 12/11/13	
		CAH_MDL2804_01110712-15	
20			
21			
22			
23			
24			

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-36	E-mail Thread	347
8		9/22/14	
9		Subject, Manufacturer	
10		Issue with Imminent	
11		Danger Definition	
12		HDA_MDL_000214864-65	
13	HDA		
14	Kelly-37	E-mail Thread	351
15		1/15/15	
16		Subject, Reintroduction	
17		Of Ensuring Patient	
18		Access and Effective	
19		Drug Enforcement Act	
20		HDA_MDL_000081283-84	
21	HDA		
22	Kelly-38	E-mail Thread	354
23		3/5/15	
24		Subject, Final Letter	
25		Of Support for Ensuring	
26		Patient Access and	
27		Effective Drug Enforcement	
28		Act of 2015	
29		HDA_MDL_000081651-54	
30	HDA		
31	Kelly-39	Statement from John	355
32		M. Gray, President and	
33		CEO HDMA	
34		4/7/14	

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-40	E-mail Thread	360
8		3/24/14	
9		Subject, Coordination	
10		Call Today?	
11		MCKMDL00651560-64	
12	HDA		
13	Kelly-41	E-mail Thread	370
14		5/1/17	
15		Subject, HDA Letters	
16		Supportive of Opioid	
17		Approaches in the States	
18		HDA_MDL_000214979-82	
19	HDA		
20	Kelly-42	E-mail Thread	375
21		8/5/08	
22		Subject, HDMA RAC	
23		Conference Call	
24		Reminder	
25		CAH_MDL2804_01364288-300	
26	HDA		
27	Kelly-43	E-mail Thread	382
28		2/9/12	
29		Subject, New DEA	
30		TPs	
31		HDA_MDL_00088099-01	
32	HDA		
33	Kelly-44	E-mail Thread	389
34		2/23/12	
35		Subject, Draft Amicus	
36		Brief Cardinal v Holder	
37		HDA_MDL_000215212-33	

1		- - -	
2		E X H I B I T S (Cont'd.)	
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	HDA		
7	Kelly-45	E-mail Thread	393
8		2/27/12	
9		Subject, Cardinal's	
10		Counsel's Comments	
11		On Amicus Brief	
12		HDL_MDL_000215970-73	
13	HDA		
14	Kelly-46	E-mail Thread	398
15		3/5/12	
16		Subject, HDMA Amicus	
17		Brief Cardinal v Holder	
18		HDA_MDL_000216300-02	
19	HDA		
20	Kelly-47	E-mail Thread	404
21		11/19/15	
22		Subject, Masters Suit	
23		Draft Amicus Outline	
24		For Your Consideration	
25		HDA_MDL_000219211-13	
26	HDA		
27	Kelly-48	E-mail Thread	406
28		1/18/16	
29		Subject, Action Requested	
30		HDMA/Masters Amicus Brief	
31		HDA_MDL_000215966-67	
32	HDA		
33	Kelly-49	E-mail Thread	408
34		4/5/16	
35		Subject, Amicus Brief	
36		Files in Masters Case	
37		HDA_MDL_000162206-56	

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E X H I B I T S (Cont'd.)
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NO.	DESCRIPTION	PAGE
HDA		
Kelly-50	E-mail Thread	412
	10/29/15	
	Subject, HDMA Amicus	
	Brief	
	HDA_MDL_000212579-16	
HDA		
Kelly-51	Letter, 4/27/84	420
	To Streck from Gitchel	
	CAH_MDL2804_02201918-20	

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DEPOSITION SUPPORT INDEX

Direction to Witness Not to Answer

PAGE LINE

None.

Request for Production of Documents

PAGE LINE

30 18

Stipulations

PAGE LINE

None.

Questions Marked

PAGE LINE

429 4

1

- - -

2

THE VIDEOGRAPHER: We are

3

now on the record. My name is

4

Daniel Holmstock. I'm the

5

videographer for Golkow Litigation

6

Services.

7

Today's date is May 10,

8

2019. The time on the video

9

screen is 8:58 a.m.

10

This deposition is being

11

held at the law offices of Baron &

12

Budd at 600 New Hampshire Avenue

13

Northwest, in Washington DC, in

14

the matter of In Re National

15

Prescription Opiate Litigation,

16

pending before the United States

17

District Court for the Northern

18

District of Ohio, Eastern

19

Division, MDL No. 2804.

20

Our deponent today is

21

Mr. Patrick Kelly, testifying in

22

his individual and 30(b)(6)

23

capacity for Healthcare

24

Distribution Alliance.

1 Counsel for appearances will
2 be noted on the stenographic
3 record.

4 The court reporter is
5 Michelle Gray who will now
6 administer the oath to the
7 witness.

8 - - -

9 ...PATRICK KELLY, having
10 been first duly sworn, was
11 examined and testified as follows:

12 - - -

13 MR. PIFKO: Can we just go
14 around the room so I know who
15 everyone is who's here. I know
16 we're going to keep -- the
17 reporter said everything would be
18 noted on the record.

19 But if everyone can
20 introduce yourself, your firm, and
21 who you represent.

22 So I'm Mark Pifko from Baron
23 & Budd on behalf of the
24 plaintiffs' executive committee.

1 MR. WEINSTEIN: Brian
2 Weinstein from Davis Polk for HDA
3 and the witness.

4 MS. MANNING: Meredith
5 Manning from Davis Polk for HDA
6 and the witness.

7 MS. GALLENAGH: Liz
8 Gallenagh, general counsel for
9 HDA.

10 MR. TOSTADO: Sergio
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17 Health.

18 MS. ADAMS: Katelyn Adams,
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18 MR. CLUFF: Sterling Cluff,
19 Baron & Budd.

20 - - -

21 EXAMINATION

22 - - -

23 BY MR. PIFKO:

24 Q. All right, Mr. Kelly. My

1 name is Mark Pifko, as you just heard.

2 We just met for the first time off the
3 record. I'm going to be asking you some
4 questions today.

5 I'm want to go over some
6 basic things before we get started.

7 A. Yeah.

8 Q. First and foremost, you are
9 under oath. So you understand that your
10 testimony here is under penalty of
11 perjury, right?

12 A. I do.

13 Q. Okay. And that means that
14 you're sworn to tell the truth, and if
15 you are intentionally misleading or
16 dishonest, you could be subject to
17 penalties from the court. Do you
18 understand that?

19 A. I understand.

20 Q. Is there any reason why
21 you're not able to give truthful and
22 accurate testimony today?

23 A. No.

24 Q. You've been deposed before,

1 correct?

2 A. Yes.

3 Q. How many times have you been
4 deposed before?

5 A. Once.

6 MS. MACKAY: Mark, I'm sorry
7 to interrupt. Can we just get on
8 the record that an objection from
9 one attorney is good for all?

10 MR. PIFKO: Yeah, that's
11 actually part of the depo
12 protocol, so we're good on that.

13 MS. MACKAY: Great, thank
14 you.

15 BY MR. PIFKO:

16 Q. So, okay, you've been
17 deposed one time before?

18 A. Correct.

19 Q. So --

20 MR. HOUTZ: This is Lester
21 Houtz on the phone from Bartlit
22 Beck for Walgreens. And I'm
23 hearing the questions fine. But I
24 cannot hear the answers at all.

1 THE VIDEOGRAPHER: The only
2 way to do that is to speak up.

3 THE WITNESS: I can speak
4 up. I'll speak up.

5 BY MR. PIFKO:

6 Q. All right. So there's no
7 reason why you can think of that your
8 deposition shouldn't proceed today?

9 A. No.

10 Q. Is there any reason why you
11 wouldn't be able to give truthful and
12 accurate testimony today?

13 A. No.

14 Q. All right. I've got some
15 materials here. I think for the most
16 part I'm going to ask you to confirm some
17 information. So as long as you're
18 truthful and honest, I think that it is
19 going to be an easy day for you.

20 You said that you were
21 deposed one other time?

22 A. Yes.

23 Q. What -- what was that?

24 A. We were deposed in the

1 Montana litigation.

2 Q. Okay. Was that -- you were
3 deposed in connection with your role for
4 the HDA?

5 A. Correct.

6 Q. And when was that?

7 A. September. I forget the
8 exact date.

9 Q. Okay. Where did that
10 happen? Was that here in DC?

11 A. Here in Washington DC.

12 Q. Okay. Was there a
13 transcript of that?

14 A. I imagine there was.

15 Q. Okay. Have you seen the
16 transcript?

17 A. I have not.

18 MR. PIFKO: Okay. We're
19 going to request a copy of that
20 just for potential impeachment
21 purposes.

22 MR. WEINSTEIN: We can talk
23 about that offline.

24 MR. PIFKO: Okay.

1 BY MR. PIFKO:

2 Q. All right. So you
3 understand that you're here to answer
4 questions and your counsel may object
5 from time to time. But unless he
6 instructs you not to answer, you're still
7 going to answer the question.
8 Understood?

9 A. Understood.

10 Q. Okay. So you understand
11 that you're here in your individual
12 capacity but you're also here as the
13 official representative of HDA with
14 respect to certain topics, correct?

15 A. I understand that, yes.

16 Q. Okay. And so that means
17 when you answer within those topics,
18 you're answering as if you are the HDA.
19 Do you understand that?

20 A. I understand that.

21 Q. Okay. I'm going to hand you
22 a copy of the notice.

23 (Document marked for
24 identification as Exhibit

1 HDA-Kelly-1.)

2 BY MR. PIFKO:

3 Q. I'm handing you what's
4 marked as Exhibit 1, which is a copy of
5 the notice that brought us here today.
6 Have you seen this before?

7 A. I have.

8 Q. When was the first time you
9 saw this?

10 A. Received it yesterday or the
11 day before in preparation for this.

12 Q. Okay. You are aware that
13 there's topics for which you're
14 designated?

15 A. Yes.

16 Q. When was the first time that
17 you became aware of the topics for which
18 you're designated?

19 A. Two days ago in preparation
20 for this.

21 Q. So the first time that you
22 had seen any of these topics was two days
23 ago?

24 A. Yes.

1 Q. And I want to turn your
2 attention to -- there's some definitions
3 in the notice, if you can flip a few
4 pages in. My -- after you get through
5 some of the initial pages, it's marked
6 Page 3.

7 A. Okay.

8 Q. Are you there?

9 A. I am.

10 Q. It says, "The terms 'you,'
11 'your,' and 'HDA.'"

12 Do you see that under D?

13 A. I do.

14 Q. Okay. That refers to HDA
15 and its predecessor organizations
16 including the Healthcare Distribution
17 Management Association and the National
18 Wholesale Druggists' Association, the
19 Western Wholesale Druggists' Association.

20 Do you see that?

21 A. I do.

22 Q. And you understand that when
23 I ask you questions today about you, I'm
24 referring to those entities, okay?

1 A. Yes.

2 MR. WEINSTEIN: Mark, I just
3 ask if there are times that you're
4 asking him in his personal
5 capacity, when you say you, if you
6 can make that clear, that would be
7 great.

8 MR. PIFKO: I think most of
9 the questions today will be
10 30(b)(6).

11 BY MR. PIFKO:

12 Q. Okay. So I want to then
13 turn your page -- or turn your attention
14 a few pages in to the topics. They start
15 on Page 5.

16 Do you see that?

17 A. I do.

18 Q. Okay. Go to Topic 4, which
19 actually is on Page 6.

20 Do you see Topic 4?

21 A. I do.

22 Q. Okay. It's about the
23 industry compliance guidelines, including
24 the development of the guidelines,

1 communications regarding the guidelines
2 and modifications, revisions or changes
3 to the guidelines, and any councils,
4 committee, task force or working groups
5 concerning the guidelines.

6 Do you see that?

7 A. I do.

8 Q. Are you prepared to provide
9 testimony on that topic today?

10 A. To the best -- to the best
11 of my ability, yes.

12 Q. Okay.

13 MR. CRAWFORD: Go ahead on
14 the phone again.

15 (Brief interruption.)

16 (Document marked for
17 identification as Exhibit
18 HDA-Kelly-2.)

19 BY MR. PIFKO:

20 Q. All right. I'm handing you
21 what's been marked as Exhibit 2, which is
22 a document Bates-labeled
23 HDA_MDL_000081363 to 81376. Have you
24 seen this before?

1 A. I have.

2 Q. Okay. This is a document
3 from Anita Ducca to you dated October 31,
4 2016. Agreed?

5 A. Yes.

6 Q. Okay. Who is Anita Ducca?

7 A. Anita Ducca is the senior
8 vice president of regulatory affairs for
9 Healthcare Distribution Alliance.

10 Q. She reports to you?

11 A. She does.

12 Q. How long have you been with
13 the HDA?

14 A. I joined in January of 2011.

15 Q. The HDA is an organization
16 that acts on behalf of its members,
17 correct?

18 A. That's correct.

19 Q. Your members include the,
20 what we refer to in the case as the big
21 three distributors, Cardinal Health,
22 AmerisourceBergen, and McKesson; is that
23 correct?

24 A. In addition to -- in

1 addition to 29 other companies, yes.

2 Q. Okay. And you also have
3 manufacturers who are members of the
4 organization, correct?

5 A. They are in a different
6 membership category, yes.

7 Q. But they are still members?

8 A. They are members in a
9 different category.

10 Q. Okay. Mallinckrodt is a
11 member?

12 A. In the affiliate member
13 category I believe so, yes.

14 Q. Okay. Purdue?

15 A. I believe so, in the -- in
16 the affiliate member category.

17 Q. Janssen and Janssen?

18 A. Johnson & Johnson?

19 Q. Sorry. Janssen -- Janssen
20 or Johnson & Johnson?

21 A. Yes, I believe in the
22 affiliate member category.

23 Q. Actavis?

24 A. Actavis, I believe so in the

1 affiliate member category.

2 Q. Teva?

3 A. I believe so.

4 Q. Endo?

5 A. I believe so.

6 Q. Okay. The HDA doesn't act
7 on it -- on its own, it acts in the
8 interest of its members and on behalf of
9 its members, correct?

10 MR. WEINSTEIN: Objection.
11 Objection to form.

12 Go ahead. You've just got
13 to give me a moment to object.

14 THE WITNESS: Sorry, I'm
15 sorry, I apologize.

16 We act on behalf of our core
17 members which are the distributor
18 members.

19 BY MR. PIFKO:

20 Q. Okay. You have a board,
21 correct?

22 A. We do.

23 Q. The board membership always
24 includes members from the big three,

1 AmerisourceBergen, McKesson, and Cardinal
2 Health, correct?

3 A. In addition to the 29 other
4 members, yes.

5 Q. Okay. But the board always
6 has somebody from those companies on it?

7 A. That's correct.

8 Q. And then there's an
9 executive committee as well, correct?

10 A. That is correct.

11 Q. And what's the makeup of the
12 executive committee?

13 A. The --

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: The executive
17 committee is seven members, three
18 members from the big three,
19 AmerisourceBergen, McKesson, and
20 Cardinal have a standing position
21 on the executive committee.

22 And then there are four
23 other positions that are other
24 member companies that filter

1 through kind of as -- as positions
2 become available, retirement, and
3 companies move on.

4 BY MR. PIFKO:

5 Q. The HDA doesn't take any
6 action without the approval of either the
7 executive committee or its board,
8 correct?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: Again, it
12 depends -- it depends on what you
13 mean by action. I mean, there are
14 certain things that rise to the
15 level of the board that require
16 their approval of expenditures, et
17 cetera. But there are day-to-day
18 operations that do not require
19 approval of the board that we
20 undertake on behalf of the
21 membership.

22 BY MR. PIFKO:

23 Q. Okay. The HDA is not going
24 to undertake any project or program

1 without approval from its executive
2 committee or the board, correct?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Again, it
6 depends on the scope of the
7 program. If there's a significant
8 cost or expenditure required, then
9 that would usually rise to the
10 level of the board. Or the
11 executive committee.

12 BY MR. PIFKO:

13 Q. The -- the HDA is not going
14 to communicate with a government agency
15 like the DEA without approval from the
16 executive committee or the board,
17 correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 THE WITNESS: And again, it
21 depends on the level of
22 communication. If it's just a
23 follow-up from a call or a
24 response to a request for

1 information, that will not
2 necessarily rise to the level of
3 the board approval and engagement.

4 BY MR. PIFKO:

5 Q. Okay. But if you're going
6 to launch some sort of detailed
7 questioning or initiative that requires
8 communication with the DEA, you're going
9 to need executive committee approval or
10 board approval, correct?

11 MR. WEINSTEIN: Objection to
12 form.

13 THE WITNESS: Again, it
14 depends on the level of -- of
15 interaction with the DEA.

16 BY MR. PIFKO:

17 Q. How about engaging with
18 members of Congress, is HDA going to
19 reach out to members of Congress without
20 approval from the board or the executive
21 committee?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: We engage

1 with, I mean, members of Congress
2 on a weekly basis through a
3 variety of fronts depending on
4 committee hearings or fundraisers
5 that we attend from our political
6 action committee.

7 And again, all of those
8 are -- we communicate those to the
9 board, but they are not decisions
10 that need to be made by the board
11 before HDA staff engage.

12 BY MR. PIFKO:

13 Q. Okay. So then that was
14 going to be my other question. When you
15 do communicate and interact with federal
16 agencies or state agencies or members of
17 Congress or any elected officials, you
18 always report back to either the board or
19 the executive committee, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: If it's -- if
23 it's relevant for board
24 consideration, yes.

1 BY MR. PIFKO:

2 Q. Or the executive committee?

3 A. Or the executive committee.

4 Q. So going back to Exhibit 2.

5 You -- Ms. Ducca says that "per your
6 request, attached is a chronology of
7 interactions with the DEA."

8 Do you see that?

9 A. I do.

10 Q. You requested that she put
11 together a chronology of HDA/DEA
12 interactions in 2016?

13 A. I don't know that I
14 requested that she put it together. I
15 know that she had been basically
16 compiling the interactions.

17 Q. Okay. So she had been
18 compiling them contemporaneously with as
19 they occurred?

20 A. Right.

21 Q. And then you asked her at
22 this point for a copy of what she had
23 prepared?

24 A. Yes.

1 Q. The -- what follows after
2 the cover e-mail, this chronology, this
3 is accurate to the best of your
4 knowledge?

5 A. To the best of my knowledge,
6 yes. Some of it does take place before I
7 joined the organization.

8 Q. But you're familiar with
9 these events?

10 A. I am.

11 Q. Okay. And in connection
12 with providing testimony today, you've
13 made yourself familiar with all these
14 events, correct?

15 A. Yes.

16 Q. Okay. We're going to be
17 talking about several of these, starting,
18 as I talked about with Topic 4, the
19 industry compliance guidelines. You're
20 familiar with those?

21 A. I am.

22 Q. And you're familiar with the
23 history of those?

24 A. Yes.

1 Q. I want to ask you about a
2 couple items on the timeline on the first
3 page here, on HDA_MDL_00081364. Are you
4 there?

5 A. I am.

6 Q. Okay. So it says,
7 "Approximately 2005, DEA begins wholesale
8 distributor meetings."

9 Do you see that?

10 A. I do.

11 Q. Okay. And then it's got
12 three other dates on the next entry. It
13 says, "DEA sends letters on quote
14 'responsibilities of controlled
15 substances distributors' for reporting
16 and preventing diversion to
17 distributors."

18 Do you see that?

19 A. I do.

20 Q. Those are what we refer to
21 as the Rannazzisi letters. Is that a
22 term that you're familiar with?

23 A. Yes.

24 Q. Okay. Do you know who

1 Mr. Rannazzisi is?

2 A. I do.

3 Q. And who was he?

4 A. He at the time was the head
5 of the office of diversion control at the
6 Drug Enforcement Administration.

7 Q. And these are letters that
8 the DEA sent out, executed by
9 Mr. Rannazzisi, informing distributors
10 and members of the pharmaceutical
11 industry of their responsibilities with
12 respect to controlled substances
13 distribution, correct?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: That's
17 correct.

18 BY MR. PIFKO:

19 Q. Okay. Then you have a,
20 "2007, DEA suspends several wholesale
21 distributor licenses."

22 Do you see that?

23 A. I do.

24 Q. Okay. I know one of those

1 was AmerisourceBergen, who entered into a
2 consent order on June 22nd, 2007. Are
3 you -- do you -- are you aware of that?

4 MS. ROLLINS: Objection to
5 form.

6 THE WITNESS: I'm aware in
7 general terms, yes.

8 BY MR. PIFKO:

9 Q. Okay. Are you aware of
10 other distributors who had their licenses
11 suspended in 2007.

12 MR. CRAWFORD: Objection to
13 form.

14 THE WITNESS: Not
15 specifically.

16 BY MR. PIFKO:

17 Q. So to your knowledge, that's
18 the only one?

19 MR. WEINSTEIN: Objection to
20 form.

21 BY MR. PIFKO:

22 Q. The AmerisourceBergen one?

23 MR. WEINSTEIN: Objection.

24 THE WITNESS: That I'm aware

1 of, yes.

2 BY MR. PIFKO:

3 Q. Okay. Go to the second page
4 of the chronology, are you there?

5 A. I am.

6 Q. Okay. It says, "Spring
7 2010, press reports of another wholesale
8 distributor registration suspension."

9 Do you see that?

10 A. I do.

11 Q. Do you know who -- whose
12 registration was suspended in the spring
13 of 2010?

14 A. I do not.

15 Q. But you know some wholesale
16 distributor's registration was
17 suspended --

18 A. According --

19 Q. -- at that time?

20 A. According to this
21 chronology, yes.

22 Q. Okay. And you believe this
23 chronology is true and correct?

24 A. To the best of my knowledge,

1 yes.

2 Q. I'm handing you what's been
3 marked as Exhibit 3.

4 (Document marked for
5 identification as Exhibit
6 HDA-Kelly-3.)

7 BY MR. PIFKO:

8 Q. It's an e-mail from Pam
9 Ritter at the HDA dated Wednesday, May
10 30th, 2007, to a whole host members of
11 the pharmaceutical industry. It's
12 Bates-labeled HSI_MDL_00620224 through
13 228.

14 MR. WEINSTEIN: You can
15 take -- take a moment.

16 BY MR. PIFKO:

17 Q. Take a moment to review that
18 and let me know when you're ready.

19 Do you know who Pam Ritter
20 is?

21 A. Yes.

22 Q. Who is Pam Ritter?

23 A. Pam Ritter was the
24 administrative assistant for the

1 department -- the government affairs
2 department at HDA.

3 Q. Okay. What's the government
4 affairs department?

5 A. The government affairs
6 department is the department that I run
7 within the organization. It is the
8 department that houses our regulatory
9 affairs, federal government affairs, and
10 state government affairs teams.

11 Q. And Pam Ritter stills work
12 at the HDA?

13 A. She is no longer employed at
14 the HDA.

15 Q. Okay. When did she leave?

16 A. She retired at the end of
17 2018.

18 Q. So have you -- you're
19 obviously are familiar with something
20 called the regulatory affairs committee?

21 A. I am, yes.

22 Q. That's a committee that's
23 within your purview?

24 A. Yes, it is.

1 Q. Okay. That -- that includes
2 some subset of members?

3 A. Yes, it does.

4 Q. Okay. But that -- at all
5 times, that includes AmerisourceBergen,
6 McKesson and Cardinal Health, correct?

7 A. If they are able to
8 participate, yes.

9 Q. Okay. But they're standing
10 members of that committee?

11 A. They -- yeah, as are the
12 rest of the members of the association,
13 yes.

14 Q. Okay. How about
15 manufacturers? Are manufacturers --

16 A. No.

17 Q. -- part of that committee?

18 A. No.

19 Q. So there's a thread of
20 e-mails here, but it goes back to one
21 dated May 25th, 2007.

22 Do you see that?

23 It's sent by Ms. Ritter, but
24 the signature on it is from Anita.

1 A. I see it.

2 Q. Okay. And it's asking for a
3 telephone call to be held.

4 A. Yes.

5 Q. Do you see that?

6 A. I do.

7 Q. Okay. And it says the
8 purpose of the call is -- I'm going to
9 quote here, it says, "At the May 17th --
10 which is 2007. "At the May 17th
11 executive committee, there was a
12 discussion about recent DEA activities to
13 involve wholesale distributors in efforts
14 to prevent diversion."

15 Do you see that?

16 A. I do.

17 Q. Did I read that correctly?

18 A. Yes.

19 Q. Okay. And as a result of
20 what HDA is calling recent DEA activities
21 to involve wholesale distributors in
22 efforts to prevent diversion, the
23 executive committee requested that HDA
24 become involved and come up with some

1 strategies to interact with DEA, correct?

2 A. Yes.

3 Q. Okay. And so it says, "In
4 consultation with our outside counsel, we
5 are looking at covering the following
6 points at such a DEA meeting."

7 Do you see that?

8 A. I do.

9 Q. Okay. It's got Items 1, 2,
10 3.

11 "One, give the DEA an
12 overview of our industry; two, discuss
13 limitations of the industry." And three,
14 which is in bold, it says, "Provide
15 specific suggestions for efforts that
16 HDMA might offer to work on with the DEA
17 as a means to show good faith and also to
18 direct them to solutions that are
19 feasible for distributors."

20 Do you see that?

21 A. I do.

22 Q. And then it says that,
23 during this call that is being requested
24 to be held in early June, it says, "We

1 particularly wish to focus on the third
2 item during this planned conference
3 call."

4 Do you see that?

5 A. I do.

6 Q. Do you agree with that?

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: I agree that's
10 what it says.

11 BY MR. PIFKO:

12 Q. That was a focus of this
13 call that was going to be held in June?

14 A. I think so. I'll take it at
15 face value. This was when I was not in
16 the organization. But, yes.

17 Q. Okay. But you are a
18 30(b)(6) representative for HDA, correct?

19 A. I am. I am. Yes, correct.

20 Q. Okay. And then at the
21 bottom here, it says, "I have attached a
22 draft list of possible suggestions."

23 Do you see that?

24 A. I do.

1 Q. Okay. And then if we can --
2 if we turn the page. We see something
3 headed "Not For External Distribution,
4 Potential Areas For Joint DEA
5 Distribution Industry Focus to Help
6 Prevent Diversion."

7 Do you see that?

8 A. On which?

9 Q. It's the fourth page in.

10 A. Titled "Not For External
11 Distribution"?

12 Q. Yes. Are you there?

13 A. Yeah, yeah, yeah. I was --
14 okay. I was reading. Okay. I see it.

15 Q. Okay. And it says -- so
16 this is the attachment from Ms. Ducca
17 where she says, "I have attached a draft
18 list of possible suggestions." This is
19 that list.

20 A. Right. I see it.

21 Q. Okay. So Number 1 is,
22 "Suggest that the distribution industry
23 work together with DEA to establish
24 guide" -- "better guidelines."

1 Do you see that?

2 A. I do.

3 Q. And then it's got some
4 sub-bullet points. Again, it talks
5 about -- it says, "A set of guidelines
6 similar to the HDMA, guidelines for
7 distribution system integrity that would
8 be used to evaluate potential pharmacy
9 customers before entering into agreements
10 to sell controlled substances to them."

11 Do you see that?

12 A. I do.

13 Q. Did I read that correctly?

14 A. Yes.

15 Q. Okay. So, these are things
16 that the HDA was considering in response
17 to what -- what she says on the prior
18 page, "This recent DEA activities to
19 involve wholesale distributors in efforts
20 to prevent diversion," correct?

21 A. Yes.

22 Q. The third one she says is,
23 "As an extreme step, are the controlled
24 substances good candidates for a

1 restricted distribution program? The
2 iPledge program is an example. Although
3 no one is very enthusiastic about such
4 programs, it might be a better
5 alternative than DEA's current efforts.
6 In such a program, pharmacies and
7 prescribers would presumably have to make
8 commitments about their practices and
9 keep specific records, and distributors
10 could not sell to anyone who did not keep
11 these commitments."

12 Do you see that?

13 A. I do.

14 Q. So that's an option that was
15 being considered at this time, correct?

16 A. Yes.

17 Q. Taking stronger compliance
18 measures is not one of the topics on
19 here, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: Not on this
23 page, no.

24 BY MR. PIFKO:

1 Q. Do you know if that was
2 something that was discussed with the
3 membership at the time?

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: I do not.

7 BY MR. PIFKO:

8 Q. So to your knowledge, taking
9 stronger compliance measures was not
10 something that was in consideration in
11 response to this DEA activities, correct?

12 MR. WEINSTEIN: Objection to
13 form.

14 THE WITNESS: Again, I don't
15 know what was discussed, whether
16 that was discussed or not. It's
17 not on this document.

18 BY MR. PIFKO:

19 Q. Okay. I'm handing you
20 what's marked as Exhibit 4.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-4.)

24 BY MR. PIFKO:

1 Q. This is another e-mail from
2 Ms. Ducca. The subject is HDMA DEA
3 strategy meeting, availability response
4 requested on alternative dates. It's
5 dated September 26, 2007. And it's got
6 another e-mail below also from Ms. Ducca
7 dated September 25, 2007.

8 MS. WICHT: Can you just
9 hold on until we have the
10 document --

11 MR. PIFKO: Yeah, no
12 problem. I was just going to -- I
13 was going to read the Bates label.

14 Bates label is
15 CAH_MDL_PRIORPROD_DEA07_00877471
16 through 473.

17 BY MR. PIFKO:

18 Q. So take a minute to review
19 it and let me know when you're ready.

20 A. Okay.

21 Q. All right. So on the first
22 page here again it's talking about
23 setting up some -- some meetings.

24 On the first page at the

1 bottom of her -- Anita Ducca's e-mail,
2 dated September 25, 2007.

3 Do you see that?

4 A. I do.

5 Q. Okay. She says, "Dear HDMA
6 committee members." So, the HDMA
7 committee members, that includes all
8 members?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: In this
12 instance it appears to be the
13 regulatory affairs committee and
14 the federal government affairs
15 committee.

16 BY MR. PIFKO:

17 Q. And it's cc'd to the
18 government public policy committee as
19 well?

20 A. Government public policy
21 council.

22 Q. Oh, council. Okay.

23 Those all include
24 representatives from all the HDA

1 distributor members?

2 A. That participate in those
3 committees, yes.

4 Q. Okay. And again, that --
5 those include members from the big three
6 distributors, correct?

7 A. Yes.

8 Q. So she says here, "Given the
9 intensity and impact of the Drug
10 Enforcement Administration's recent
11 actions, and the concerns expressed by
12 HDMA's executive committee last week,
13 HDMA recommends developing a
14 comprehensive DEA strategy."

15 Do you see that?

16 A. I do.

17 Q. So at this time, the HDA on
18 behalf of its members was developing a
19 comprehensive DEA strategy as a result of
20 what they understood to be an -- intense
21 actions from the DEA; is that correct?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Yes, that is

1 correct.

2 BY MR. PIFKO:

3 Q. And then if you go to the
4 second page of the document, she outlines
5 some of the topics of discussions.

6 Do you see that?

7 A. I do.

8 Q. Okay. So she says, "Our
9 initial thoughts are" -- I'm on the
10 second paragraph at the top there. Are
11 you with me?

12 A. Yes, I am.

13 Q. She says, "Our initial
14 thoughts are to review the major DEA
15 issues."

16 Do you see that?

17 A. I do.

18 Q. And then she has in
19 parentheses what those issues are, right?

20 A. Yes.

21 Q. And one of them is
22 suspicious orders, correct?

23 A. Yes.

24 Q. And then she says, she wants

1 to develop a specific policy and
2 positions and supporting information for
3 those issues.

4 Do you see that?

5 A. Yes.

6 Q. As well as an overall
7 strategy for identifying solutions.

8 Do you see that?

9 A. I do.

10 Q. "We would also
11 comprehensively assess HDMA's role in
12 future DEA interactions."

13 Do you see that?

14 A. I do.

15 Q. I said that correctly?

16 A. Yes, you did.

17 Q. Okay. So then she says,
18 "Specific topics could include." And
19 there are several bullet points here.

20 Do you see that?

21 A. I do.

22 Q. So she says, "For suspicious
23 orders," she says, are -- I'm reading the
24 second bullet point. "Are there

1 alternatives we can propose to DEA, or
2 specific objections we should raise?
3 What supporting information exists? Can
4 we develop a strategy for DEA's concerns?
5 Who should be involved?"

6 Do you see that?

7 A. Yes.

8 Q. So, again, there was a
9 discussion within the HDMA and its
10 members at this time about a strategy for
11 communicating with DEA, correct?

12 A. Yes.

13 Q. Another -- the
14 second-to-last bullet point, she has
15 here, she says, "What, if any, legal
16 options do we have to address all of the
17 above?"

18 Do you see that?

19 A. I do.

20 Q. So in addition to a DEA
21 strategy, HDMA and its members at this
22 time were also evaluating legal options
23 they might have to address these issues,
24 correct?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: According to
4 this, yes.

5 BY MR. PIFKO:

6 Q. You don't have any reason to
7 dispute the accuracy of this?

8 A. I don't.

9 (Document marked for
10 identification as Exhibit
11 HDA-Kelly-5.)

12 BY MR. PIFKO:

13 Q. I'm handing you what's
14 marked as Exhibit 5. It is a single-page
15 e-mail. It's Bates-labeled
16 HDA_MDL_000213427. Take a minute to
17 review it and let me know when you're
18 ready.

19 A. Okay.

20 Q. There's two e-mails in here,
21 only really one of substance. The
22 substantive e-mail is from John Gray
23 to -- is it Paul Julian dated Tuesday,
24 October 30th, 2007, and then John Gray

1 forwards that to Scott Melville.

2 Do you see that?

3 A. I do.

4 Q. And the subject is HDMA
5 board meeting.

6 Do you see that?

7 A. Yes.

8 Q. Okay. Who's John Gray?

9 A. John Gray is the president
10 and CEO of HDA.

11 Q. To your knowledge, how long
12 has he been in that role?

13 A. Since 2004 I believe, maybe
14 '3.

15 Q. So at this time, he was
16 president and CEO of HDA?

17 A. HDMA at the time, yes.

18 Q. Okay. And do you know who
19 Paul Julian is?

20 A. Paul Julian was the board
21 member that was tasked to basically
22 represent McKesson on the HDA Board of
23 Directors.

24 Q. Okay. And then John Gray

1 forwards this exchange to Scott Melville.

2 Do you see that?

3 A. I do.

4 Q. Do you know who Scott
5 Melville is?

6 A. I do.

7 Q. Who is he?

8 A. Scott Melville was the
9 former head of the government affairs
10 department at HDA.

11 Q. Is Scott Melville still
12 there?

13 A. He is not.

14 Q. So did you take over his
15 position?

16 A. I did.

17 Q. And Anita Ducca reported to
18 him at this time?

19 A. She did.

20 Q. So John Gray writes to Paul.
21 He says, among other things, if you are
22 -- are you there?

23 A. I am.

24 Q. "The DEA issue concerning

1 the recent surge in DEA enforcement
2 around suspicious orders and methadone
3 was moved to the top of the HDMA priority
4 list."

5 Do you see that?

6 A. I do.

7 Q. Do you agree that the DEA
8 issue concerning what they call -- he
9 calls a recent surge in enforcement
10 around suspicious order was a top
11 priority of the HDMA at the time?

12 A. I do.

13 Q. He says, "The board wants
14 the association" -- that means the HDA,
15 correct?

16 A. Yes.

17 Q. -- "to quickly develop a
18 plan to deal with and work with the DEA
19 as necessary."

20 Do you see that?

21 A. I do.

22 Q. So there was discussions to
23 develop a plan to deal with the DEA at
24 this time, correct?

1 A. Yes.

2 Q. In response to this recent
3 surge in enforcement around suspicious
4 orders, correct?

5 A. Yes.

6 Q. Then he says, "Our first
7 step will be to assemble a legal task
8 force of member company attorneys
9 (inhouse or outside counsel) to meet with
10 our staff and discuss a course of action
11 with the DEA."

12 Do you see that?

13 A. I do.

14 Q. Then he says, "Is there
15 someone within your McKesson legal team
16 that could participate on this task
17 force?"

18 Do you see that?

19 A. I do.

20 Q. Are you aware of whether
21 such a task force was in fact formed?

22 A. Not specifically. I know
23 there were subsequent groups that were
24 formed, but I don't know if there was a

1 legal task force. In fact, I'm not aware
2 of a legal task force that was formed
3 specifically for this purpose.

4 Q. Okay. Are you aware that
5 either inhouse or outside counsel from
6 HDMA's distributor members participated
7 in discussions about this surge in DEA
8 enforcement around suspicious orders?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: Not specific
12 meetings.

13 BY MR. PIFKO:

14 Q. But you don't have any
15 reason to disagree with this?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: I don't.

19 BY MR. PIFKO:

20 Q. Did Anita Ducca tell you
21 that there was no such group?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: She did not.

1 BY MR. PIFKO:

2 Q. Is Anita Ducca the person
3 who would know for sure whether such a
4 group was formed?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: I can't say
8 for certain whether she would know
9 or not.

10 (Document marked for
11 identification as Exhibit
12 HDA-Kelly-6.)

13 BY MR. PIFKO:

14 Q. I'm handing you what's been
15 marked as Exhibit 6. Exhibit 6 is a
16 PowerPoint presentation Bates-labeled
17 HDA_MDL_000143030 through 043 or 143043.

18 According to the metadata,
19 which is attached on the first page of
20 this document, it was last modified
21 December 10th, 2007, and the file name
22 was slide for -- "Slides for Packaging
23 Call, 12/10/2007."

24 Take a minute to review this

1 and let me know when you're ready.

2 You're of course free to
3 review as much of the document as you see
4 fit, but I'm only going to ask you about
5 a couple pages of it.

6 A. Okay.

7 Q. Are you familiar with the
8 format of these slides? Is that the HDMA
9 logo on the bottom?

10 MR. WEINSTEIN: Objection to
11 form.

12 THE WITNESS: I -- I am --
13 yes, that is a common slide format
14 that we have used.

15 BY MR. PIFKO:

16 Q. And when you have these
17 conference calls, sometimes they have
18 webinars or you share the PowerPoint
19 presentations with people and you go
20 through them when you have a call?

21 A. Sometimes.

22 Q. Okay. This is the kind of
23 PowerPoint that you might share with your
24 members during a call?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: It could be.
4 I don't know if this specific
5 PowerPoint was shared with members
6 or not. In fact, I'm not even
7 sure who the author is. I can't
8 imagine --

9 BY MR. PIFKO:

10 Q. That was going to my -- be
11 my next question. Do you know who
12 K. Baskette is?

13 A. I do not.

14 Q. This was produced by HDMA,
15 do you have any reason to dispute the
16 authenticity of this document?

17 A. I do not.

18 Q. The first slide here says,
19 "Tomorrow's Outcome?"

20 Do you see that?

21 A. Yes.

22 Q. "What are the impacts on our
23 members?"

24 Do you see that?

1 A. I do.

2 Q. "Can we identify common
3 themes and problems?"

4 Do you see that?

5 A. I do.

6 Q. And then it says, "Should
7 we," and it's got some bullet points.

8 Do you see that?

9 A. Yes.

10 Q. One of them is, "Challenge
11 the DEA."

12 Do you see that?

13 A. Yes.

14 Q. At this time in late 2007 in
15 response to this surge in enforcement
16 activity, one of the strategies HDMA and
17 its members were considering was to
18 challenge the DEA, correct?

19 MR. WEINSTEIN: Objection to
20 form.

21 THE WITNESS: Yes.

22 BY MR. PIFKO:

23 Q. It says on the next page,
24 "DEA will be here to describe their

1 expectations."

2 Do you see that?

3 A. I do.

4 Q. And it -- it gives some
5 examples of what HDA understands their
6 expectations to be at this time.

7 Do you see that?

8 A. Yes.

9 Q. "Know your customer better,"
10 correct?

11 A. That's what it says.

12 Q. "Have processes/controls in
13 place to detect suspicious orders,"
14 correct?

15 A. Yes.

16 Q. "Stop 'suspicious' order
17 sales" -- underlined -- "before
18 shipment."

19 Do you see that?

20 A. Yes.

21 Q. That's correct?

22 A. Yes.

23 Q. "Less interested in reports
24 after shipment."

1 Do you see that?

2 A. Yes. That's what it says,
3 yes.

4 Q. Turn to the third page of
5 the document, of the -- the slides. So
6 it's technically the fourth page of the
7 document. "Suspicious orders - policy
8 questions" is the heading of the slide.

9 Do you see that?

10 A. I do.

11 Q. Halfway down the slide it
12 says, "Should we support DEA's efforts?"

13 Do you see that?

14 A. Yes.

15 Q. So there are some questions
16 about whether HDMA and its members were
17 going to support DEA's efforts, correct?

18 A. Yes.

19 MS. MACKAY: Object to form.

20 MR. WEINSTEIN: Objection to
21 form. Just got to give a second
22 after the question.

23 THE WITNESS: Oh, I'm sorry.

24 BY MR. PIFKO:

1 Q. One of the bullet points is,
2 "Develop business practices," which is --
3 business practices is in quote.

4 Do you see that?

5 A. I do.

6 Q. Do you now understand what
7 that refers to?

8 A. I -- I think what it led to,
9 yes.

10 Q. The industry compliance
11 guidelines, correct?

12 A. Yes.

13 Q. And then it says,
14 "Alternatively do we want to challenge
15 DEA's expectations?"

16 Do you see that?

17 A. Yes.

18 Q. And that was something else
19 HDMA and its members were considering at
20 this time, correct?

21 MS. MACKAY: Object to form.

22 THE WITNESS: Again, I think
23 there was a variety of
24 considerations going on at the

1 time, yes.

2 BY MR. PIFKO:

3 Q. But this was one of them,
4 correct?

5 A. According to this, yes.

6 Q. Again, it says, "What are
7 our legal options?"

8 Do you see that?

9 A. I do.

10 Q. So there were some
11 evaluations of what legal strategies can
12 be employed to challenge the DEA's
13 expectations?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: Again, I think
17 those considerations were being
18 discussed.

19 (Document marked for
20 identification as Exhibit
21 HDA-Kelly-7.)

22 BY MR. PIFKO:

23 Q. I'm handing you what's
24 marked as Exhibit 7, it is a two-page

1 document. It's a letter on HDMA
2 letterhead dated July 25, 2007, from
3 Scott Melville. It's Bates-labeled
4 CAH_MDL2804_02489197, through 198. Take
5 a minute to review that and let me know
6 when you're done.

7 A. Okay.

8 Q. So this is -- this letter
9 Exhibit 7 is HDMA requesting a meeting
10 with DEA to discuss suspicious orders,
11 correct?

12 A. Correct.

13 Q. This is -- it's dated
14 July 25, 2007. That's approximately a
15 month after AmerisourceBergen entered --
16 entered into a consent order with the
17 DEA, correct?

18 MS. ROLLINS: Objection to
19 form.

20 THE WITNESS: I'll take -- I
21 don't know the specific date when
22 that consent decree was entered
23 into. I'm thinking it's in that
24 time frame.

1 BY MR. PIFKO:

2 Q. Okay. So you agree it's
3 roughly within that time frame?

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: I'll agree
7 that it was in that time frame.

8 BY MR. PIFKO:

9 Q. At the bottom of the first
10 page of the letter, HDMA tells DEA, "Our
11 objective is to find an effective process
12 for the DEA and our members to achieve
13 the common goals of reducing the
14 potential for diversion in a less
15 adversarial environment."

16 Do you see that?

17 A. I do.

18 Q. That's what HDMA told DEA at
19 this time, correct?

20 A. It's in the letter that we
21 sent to DEA, yes.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-8.)

1 BY MR. PIFKO:

2 Q. I'm handing you a single
3 page e-mail from Ms. Ducca marked as
4 Exhibit 8. It's Bates-labeled
5 CAH_MDL2804_012489160.

6 It's from Ms. Ducca dated
7 October 28, 2011, to Cardinal Health's
8 Robert Giacalone.

9 A. Giacalone.

10 Q. Giacalone.

11 Take a minute to review it,
12 and I just have a couple questions about
13 this.

14 A. Okay.

15 Q. So in it, Ms. Ducca is
16 explaining the history of some of the
17 negotiations and discussions regarding
18 the industry compliance guidelines,
19 correct?

20 A. Yes.

21 Q. Okay. And you could see
22 from the e-mail there are several
23 attachments, if you look on the header.

24 A. I see that.

1 Q. Okay. And then she says,
2 there's there -- there were three
3 meetings with DEA on the ICG guidelines,
4 one, April 15, 2008, one June 4, 2008,
5 one in September 2008.

6 Do you see that?

7 A. I do.

8 Q. And then she says she
9 attached a summary of the first one.

10 Do you see that?

11 "I've included a summary of
12 the first one."

13 A. Yes, yes.

14 Q. And then she says, "Labeled
15 draft since I didn't want it to look
16 final if it ever 'got out.'"

17 Do you see that?

18 A. I do.

19 Q. And then she says, "Also,
20 the second meeting consisted of DEA
21 giving us verbal feedback on their review
22 of the draft ICG that we gave them."

23 Do you see that?

24 A. I do.

1 Q. "This is, therefore, a
2 summary of that feedback."

3 Do you see that?

4 A. I do.

5 Q. "Again, we never called it
6 'final' since I was more interested in
7 finishing the ICG than in perfecting a
8 summary."

9 Do you see that?

10 A. I do.

11 Q. "For the third meeting I
12 didn't do a summary," she says.

13 Do you see that?

14 A. I do.

15 Q. And then she says, "Also
16 included is a summary of a meeting HDMA
17 had with DEA in September of '07 just to
18 ask them what was going on with their
19 meetings with distributors."

20 Do you see that?

21 A. I do.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-9.)

1 BY MR. PIFKO:

2 Q. I'm going to hand you some
3 of the attachments, starting with her
4 summary of the September 7th, 2007,
5 meeting with DEA. Exhibit 9.

6 This is a two-page document,
7 Exhibit 9, Bates-labeled
8 CAH_MDL2804_02489199 through 200. Take a
9 minute to review this. And let me know
10 when you're done.

11 A. Okay.

12 Q. This was the meeting that
13 was held in response to the request that
14 HDA made on July 25th, 2007, correct?
15 This is a summary of that meeting,
16 correct?

17 A. I believe so, yes.

18 Q. Which is referred to in
19 Exhibit 7, right? That's the letter.

20 A. Yes.

21 Q. Okay.

22 MR. WEINSTEIN: It says
23 July 25, 2008, on the record here.
24 But it's 2007, just to be clear.

1 MR. PIFKO: Oh, I said that,
2 okay.

3 MR. WEINSTEIN: Yeah, yeah.

4 BY MR. PIFKO:

5 Q. So this meeting included,
6 from HDMA, Scott Melville, Anita Ducca,
7 and David Durkin, who's outside counsel
8 for HDA, correct?

9 A. Correct.

10 Q. And DEA attendees included
11 Mark Caverly, Cathy Gallagher, Mike
12 Mapes, and Lisa Sullivan, correct?

13 A. Correct.

14 Q. So it's got different
15 headings, summary, key takeaways,
16 additional points DEA made included,
17 conclusion, and then HDMA questions and
18 assessment.

19 Do you agree those are the
20 headings she has?

21 A. I agree.

22 Q. In her summary section on
23 the first page -- so one of the things
24 that HDA requested in the July 25th,

1 2007, letter, Exhibit 7, was to
2 understand the -- what we called the
3 distributor initiative. And there is
4 some discussion here that Mike Mapes
5 provided about that.

6 Do you see that?

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: Yes.

10 BY MR. PIFKO:

11 Q. Okay. So the summary that
12 Ms. Ducca prepared says that, "Mr. Mapes
13 noted that DEA had met with approximately
14 15 to 20 wholesale distributors one on
15 one. They had prioritized who to meet
16 with on a combination of wholesale
17 distributor sales volume and tracing back
18 to where they felt the source of products
19 for illicit internet pharmacies were
20 located."

21 Do you see that?

22 A. I do.

23 Q. Do you have any reason to
24 dispute that that's what DEA told HDMA

1 during this meeting?

2 A. I do not.

3 Q. Then she says, key takeaways
4 from the meetings are -- from the meeting
5 were, first bullet point, "DEA's policy
6 was to expect more than just reporting
7 suspicious orders."

8 Do you see that?

9 A. I do.

10 Q. Second bullet point, "Simply
11 complying with the 'suspicious orders'
12 regulatory requirement does not mean, in
13 the agency's view, that the registrant is
14 making" -- "maintaining an effective
15 program to detect and prevention
16 diversion."

17 Do you see that?

18 A. I do.

19 Q. Did I read that correctly?

20 A. You did.

21 Q. Third bullet point, "DEA
22 indicated that they did not have the
23 resources to inspect every pharmacy;
24 therefore, it was important for the

1 distributor to 'know their customers.'"

2 Do you see that?

3 A. I do.

4 Q. Do you have an -- any reason
5 to dispute that these were key takeaways
6 from the meeting?

7 A. I do not.

8 Q. Then she has under her
9 heading additional points DEA made
10 included.

11 Do you see that?

12 A. Yes.

13 Q. The second one says, "DEA
14 provided examples of what a
15 distributor" -- "a wholesale distributor
16 should do to 'know their customers' and
17 what to look for."

18 Do you see that?

19 A. I do.

20 Q. Do you have any reason to
21 dispute that DEA during this meeting
22 provided examples of what distributors
23 should do to know their customers?

24 A. I do not.

1 Q. Going to the second page,
2 second-to-last bullet point at the top of
3 that page, "DEA also indicated that they
4 were not going to make a decision for the
5 wholesale distributor as to when an order
6 was suspicious."

7 Do you see that?

8 A. I do.

9 Q. "They feel this is up to the
10 distributor."

11 Do you see that?

12 A. I do.

13 Q. Do you have any reason to
14 dispute that this is what DEA told HDMA
15 during this meeting?

16 A. I do not.

17 Q. Last bullet point. "DEA
18 suggested that distributors should check
19 on the pharmacies' prescribing
20 physicians. They pointed to some states
21 having online systems by which a
22 distributor could check to see if a
23 prescribing physician had a valid DEA
24 registration. DEA suggested that

1 distributors ask who the doctors are that
2 are prescribing, where the pharmacy is
3 geographically with respect to its
4 prescribing doctors, and the patient
5 population."

6 Do you see that?

7 A. I do.

8 Q. Any reason to dispute that
9 that's something that DEA told HDMA
10 during this meeting?

11 A. I do not.

12 Q. And per the normal practice,
13 HDMA would have communicated this
14 information back to its members after the
15 meeting occurred, correct?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: Correct.

19 (Document marked for
20 identification as Exhibit
21 HDA-Kelly-10.)

22 BY MR. PIFKO:

23 Q. I'm handing you what's
24 marked as Exhibit 10. For the record,

1 it's a multiple-page document
2 Bates-labeled HDA_MDL_000151104 through
3 151118. Take a minute to review
4 Exhibit 10 and let me know when you're
5 ready.

6 MR. WEINSTEIN: I think I
7 have the last Bates as 119, just
8 for the record.

9 MR. PIFKO: Oh, I did -- I
10 skipped that. Sorry. I didn't
11 see that was there. Yeah, so it
12 goes through 119.

13 THE WITNESS: Okay.

14 BY MR. PIFKO:

15 Q. Are you ready?

16 A. Yes.

17 Q. So as we discussed when we
18 looked at Exhibit 3, in response to what
19 HDMA told its members was a recent DEA
20 activities to involve wholesale
21 distributors in efforts to prevent
22 diversion, HDMA and its members were
23 discussing putting together some best
24 practices or guidelines concerning

1 suspicious orders, correct?

2 A. Correct.

3 Q. And ultimately HDMA and its
4 members decided to move forward with that
5 project, correct?

6 A. Correct.

7 Q. If you look back at
8 Exhibit 9, in her summary, Ms. Ducca
9 references that, she says that "DEA
10 provided us with their latest
11 organizational chart," on the first page.
12 I don't know if you see that there. And
13 explained the responsibilities of each
14 section.

15 A. Yes.

16 Q. Okay. So going to
17 Exhibit 10, this is -- Exhibit 10 is
18 Ms. Ducca on Wednesday, January 2, 2008,
19 sending to a consultant HDMA hired on
20 behalf of its members to put together
21 this best practices, some background
22 information and a scope of work, correct?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: Correct.

2 BY MR. PIFKO:

3 Q. The consultant, his name was
4 Bill Wilson, correct?

5 A. Yes.

6 Q. She says, "Dear Bill, please
7 find the information we discussed."

8 Do you see that?

9 A. I do.

10 Q. "The last attachment
11 contains" -- "contains the 'scope of
12 work' for the project proposal."

13 Do you see that?

14 A. I do.

15 Q. The second page of this
16 document includes the -- this org chart
17 which came from the meeting with DEA,
18 correct?

19 A. Yeah. I imagine so, yes.

20 Q. And then if you turn a few
21 more pages in. So Ms. Ducca is including
22 some information that she says that --
23 background that this consultant might
24 need for his work, correct?

1 A. Correct.

2 Q. One of them is a
3 September 27, 2006, letter from
4 Mr. Rannazzisi, correct?

5 A. Correct.

6 Q. There are several pages that
7 are redacted. And then the last three
8 pages are the scope of work for this
9 consultant, correct?

10 A. Yes.

11 Q. On the first page of the
12 scope of work, which is HDMA --
13 HDA_MDL_000151117, she provides different
14 headings.

15 One of -- the number -- the
16 second heading is "Objectives."

17 Do you see that?

18 A. I do.

19 Q. Okay. And she says, "The
20 purpose of this project is to support
21 HDMA's efforts to aid its members in
22 responding to the drug enforcement
23 distributor initiative by preparing a
24 'model' set of suspicious order business

1 practices."

2 Do you see that?

3 A. I do.

4 Q. Do you agree that that was
5 the scope of work for this project?

6 A. I do at the time. Yes.

7 Q. Okay. So, she says, "The
8 final product will be a document
9 containing the business practices in the
10 form of a white paper that will" --

11 Do you see that?

12 A. I do.

13 Q. And then she's got four
14 letter points here.

15 Do you see that?

16 A. I do.

17 Q. The first one I'm
18 paraphrasing is for -- to serve as a
19 guide for evaluating the suitability of
20 distributor's customers.

21 Do you see that?

22 A. I do.

23 Q. That's correct?

24 A. Yes.

1 Q. Okay.

2 A. Stability and suitability of
3 distributor's customers.

4 Q. The second goal of this
5 document is Letter B here, "Provide
6 guidance to healthcare distributors on
7 evaluating customer orders for controlled
8 substances to indicate when orders are
9 suspicious."

10 Do you see that?

11 A. I do.

12 Q. That's correct?

13 A. That's what it says.

14 Q. And that's one of the goals
15 of the final product?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: It is my
19 understanding.

20 BY MR. PIFKO:

21 Q. The third one, Letter C, is,
22 "Define criteria for use by HDMA members
23 that would signal when a customer is
24 placing a suspicious order and whether

1 there should be further evaluation."

2 Do you see that?

3 A. I do.

4 MS. MACKAY: Object to form.

5 BY MR. PIFKO:

6 Q. That's correct, that was one
7 of the goals of this white paper?

8 A. That's what it states here.

9 Q. Do you have any reason to
10 dispute that was one of the goals?

11 A. I do not.

12 Q. Okay. And then the fourth
13 one is, "Suggest criteria and mechanisms
14 for healthcare distributors to design of
15 a system to stop orders prior to
16 shipment, if/when an order is determined
17 to be suspicious."

18 Do you see that?

19 A. I do.

20 Q. That was another goal of
21 this model set of suspicious order
22 business practices, correct?

23 A. Again, that's what it says
24 here, and I have no reason to dispute it.

1 Q. So going to the -- the
2 second page of the scope of work.
3 HDA_MDL_001511178. Are you there?

4 A. I am.

5 Q. The heading starts on the
6 prior page, but she says, "Background
7 information and research will include the
8 following components."

9 And then she's got letters A
10 through E.

11 Do you see that?

12 A. I do.

13 Q. Okay. So these are things
14 that the consultant is supposed to do in
15 order to put together these model set of
16 suspicious order business practices,
17 correct?

18 A. Yes.

19 Q. Okay. So one of them is to
20 evaluate DEA regulations and guidance
21 provided to healthcare distributors.

22 Do you see that?

23 A. I do.

24 Q. This includes historic

1 information, the controlled substances
2 manual, a report to the Department of
3 Justice on suspicious orders for listed
4 chemical handlers, and more recent DEA
5 guidelines -- or guidance such as the
6 2006 Rannazzisi letter, Kyle Wright's
7 presentation to the HDMA.

8 Do you see that?

9 A. Yes.

10 Q. Okay. That was one of the
11 things that this consultant was supposed
12 to look at to prepare these, correct?

13 A. Yes.

14 Q. Another thing was, it says,
15 "Obtaining where available copies of HDMA
16 member companies' internal suspicious
17 order business practices."

18 Do you see that?

19 A. I do.

20 Q. So one of the things that
21 this consultant was supposed to do was
22 collect the suspicious order business
23 practices from HDMA members, correct?

24 MR. WEINSTEIN: Objection to

1 form.

2 MS. MACKAY: Objection to
3 form.

4 THE WITNESS: It says where
5 available, yes.

6 BY MR. PIFKO:

7 Q. And then it says,
8 "Interviewing at least eight, as many as
9 ten, HDMA member companies."

10 Do you see that?

11 A. I do.

12 Q. And then it's got several
13 bullet points about what the interviews
14 are supposed to include.

15 Do you see that?

16 A. I do.

17 Q. One of them is, "Identify
18 preferences for content of such
19 guidances."

20 Do you see that?

21 A. I do.

22 Q. Another one is, "Define a
23 mechanism for stopping shipments that are
24 suspicious before they are released from

1 a warehouse."

2 Do you see that?

3 A. I do.

4 Q. "Identify information that
5 is either nonessential, unsuitable or
6 lacks flexibility to be applicable across
7 HDMA's highly varied membership."

8 Do you see that?

9 A. I do.

10 Q. Those were all things that
11 the consultant was supposed to discuss in
12 his interviews with the member companies?

13 A. That's what this stipulates,
14 yes.

15 Q. Then another thing he was
16 supposed to consider was, "Input from
17 HDMA's outside counsel."

18 Do you see that?

19 A. I do.

20 Q. It says, "HDMA's outside
21 counsel is currently preparing
22 information pertaining to suspicious
23 order business practices."

24 Do you see that?

1 A. Best practices, yes.

2 Q. "The information being
3 prepared is based on his experience with
4 HDMA members and DEA expectations and it
5 is anticipated will address some of the
6 conditions that should be built into a
7 set of suspicious order business
8 practices."

9 Do you see that?

10 A. Yes.

11 Q. So that's another thing this
12 consultant was supposed to be
13 considering?

14 A. According to this, yes.

15 Q. Any reason to dispute that?

16 A. No.

17 Q. Letter E is, "Review of
18 previous HDMA guidelines and other
19 HDMA-generated materials pertaining to
20 suspicious orders and related compliance
21 programs."

22 Do you see that?

23 A. I do.

24 Q. You're aware that at this

1 time, HDMA had other guidelines for
2 suspicious orders, correct?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: I don't know
6 that there were other guidelines
7 for suspicious orders.

8 BY MR. PIFKO:

9 Q. Okay. We'll get to that in
10 a minute. Then it says underneath there,
11 "To the extent possible, the final
12 document should be designed in
13 recognition of the highly varying nature
14 of the wholesale distribution in terms of
15 individual HDMA member size, customer
16 base and needs, physician" -- "physical
17 location, information technology, et
18 cetera."

19 Do you see that?

20 A. I do.

21 Q. So you understood that these
22 guidelines were supposed to be adaptable
23 so that they could be implemented by any
24 of HDA's members, correct?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: Correct.

4 BY MR. PIFKO:

5 Q. So then item 4, she has is,
6 project steps, cost and timing. So the
7 first step is designed to -- she wants
8 the consultant to design the interview
9 instrument.

10 Do you see that?

11 A. I do.

12 Q. And then if we turn the
13 page, the next step is contacting HDMA
14 members to request copies of their
15 current suspicious orders business
16 practices.

17 Do you see that?

18 A. I do.

19 Q. So we discussed this before.
20 This was Item B as some of the documents
21 that the consultant was supposed to use
22 to develop these, correct?

23 A. Yes.

24 Q. And then she says, "HDMA can

1 facilitate this by sending an e-mail to
2 our members making the request."

3 Do you see that?

4 A. I do.

5 Q. So you understand that and
6 agree that HDMA was going to request
7 copies of its members' suspicious order
8 business practices so that they could be
9 used for this project, correct?

10 MS. MACKAY: Objection to
11 form.

12 THE WITNESS: That's what I
13 understand, yes.

14 BY MR. PIFKO:

15 Q. And then it says, "Identify
16 an appropriate individual within the
17 company with whom to conduct the
18 interview as described in 3-C above."

19 Do you see that?

20 A. Yes, I do.

21 Q. And then conduct the
22 interview, right?

23 A. Yes. I see that.

24 Q. Okay. And so -- and then

1 Item 3 was to then put pen to paper and
2 draft the guidelines, correct?

3 A. Item -- yes, Item 3, yes,
4 prepare the draft.

5 Q. And then she sets a deadline
6 of January 30th so that HDMA staff
7 committees and outside counsel can review
8 them, correct?

9 A. That's what it says, yes.

10 Q. And then she says, "There
11 may be some meetings with the government
12 and public policy council which is
13 scheduled for February 12th and 13th, and
14 maybe he needs to participate in those
15 meetings."

16 Do you see that?

17 A. I do.

18 Q. And then there's going to
19 be -- they are going to be discussing the
20 draft and obtaining feedback from the
21 committee, correct?

22 A. That's what it says.

23 Q. Then to the extent
24 necessary, Items 5 and 6 talk about how

1 the consultant might need to make
2 revisions to the draft, agree?

3 A. Agree.

4 MR. WEINSTEIN: Mark, is
5 this a good time for a break?
6 We've been going about an hour and
7 a quarter.

8 MR. PIFKO: Sure.

9 THE VIDEOGRAPHER: The time
10 is 10:10 a.m. We are going off
11 the record.

12 (Short break.)

13 THE VIDEOGRAPHER: The time
14 is 10:24 a.m. We are back on the
15 record.

16 (Document marked for
17 identification as Exhibit
18 HDA-Kelly-11.)

19 BY MR. PIFKO:

20 Q. I'm handing you what's
21 marked as Exhibit 11. For the record,
22 it's a document, a few pages long, with
23 the heading "NWDA Suspicious Order
24 Monitoring System." It's Bates-labeled

1 CAH_MDL2804_02201910 through 1916.

2 MR. WEINSTEIN: Is there a
3 date on this document, Mark?

4 MR. PIFKO: Not on this one.

5 BY MR. PIFKO:

6 Q. Take a minute to review this
7 and let me know when you're done. Before
8 you get mired in the details -- take as
9 much time as you need -- I just want to
10 confirm.

11 So as we know from the other
12 e-mails and discussion on this best
13 practices guidelines issue, the HDA's
14 predecessor had some sort of other
15 suspicious order monitoring guidelines,
16 correct?

17 MR. WEINSTEIN: Objection to
18 form.

19 MR. PADGETT: Object to
20 form.

21 MS. WICHT: Object to the
22 form.

23 THE WITNESS: Again, I've
24 not seen this before. But I will

1 take you at your word, yes.

2 BY MR. PIFKO:

3 Q. Well, she comments that one
4 of the things in Exhibit 10 that he's
5 supposed to review is the previous HDMA
6 guidelines.

7 Do you recall that?

8 MR. WEINSTEIN: Where are
9 you referring to, Mark?

10 MR. PIFKO: On Exhibit 10,
11 in the scope of work Section 3-E.
12 For the record, that's on
13 HDA_MDL_000151118.

14 BY MR. PIFKO:

15 Q. My question is, you agree
16 there were previous guidelines. She
17 makes reference to it in the scope of
18 work here, correct?

19 A. She did make -- I agree she
20 did make a reference to it. And this is
21 an example of those guidelines, I
22 imagine. Yes.

23 Q. To your knowledge, these are
24 dated around the '80s?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: I have -- I
4 have no idea when these are dated.

5 BY MR. PIFKO:

6 Q. Okay. Did you discuss
7 these, or any prior HDA or its
8 predecessor entity guidelines in
9 preparing for depositions with anybody?

10 A. I have not seen this
11 document before.

12 Q. Did you undertake any effort
13 to familiarize yourself with HDA's prior
14 suspicious order guidelines in connection
15 with preparing for this deposition?

16 A. Other than the ICGs, no,
17 nothing.

18 Q. NWDA is a predecessor name
19 for HDA correct?

20 A. That's correct.

21 Q. National Wholesale
22 Druggists' Association, correct?

23 A. Correct.

24 Q. Okay. Do you have any

1 reason to dispute that these are
2 guidelines put out on suspicious order
3 monitoring, put out by the NWDA?

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: I have no
7 reason to dispute that.

8 BY MR. PIFKO:

9 Q. I want to direct your
10 attention -- well --

11 A. Can I read them?

12 Q. Yeah. Sure I didn't know if
13 you were ready. I was only going to ask
14 you about a couple pages.

15 A. Okay.

16 Q. But take your time to look
17 at it as much as you need.

18 A. Okay.

19 Q. You ready?

20 A. I am.

21 Q. All right. First page,
22 Section 1, "Background." It says it's --
23 "It is the responsibility of the
24 wholesaler to design and operate a system

1 which will disclose to the wholesaler
2 suspicious orders of controlled
3 substances."

4 Do you see that?

5 A. I do.

6 Q. Do you have an understanding
7 that that is something that wholesale
8 distributors are required to do?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: I do.

12 BY MR. PIFKO:

13 Q. Then it -- a little bit
14 further down in that paragraph, it says,
15 "The requirement is to monitor individual
16 orders by measuring dosage units within
17 each order and to examine for suspicious
18 volumes. Special emphasis should be
19 placed on unusual or sudden increases
20 with the volume of invoice lines
21 processed by the average wholesaler.
22 This task becomes increasingly difficult
23 as the number of products and dosage
24 sizes increase."

1 Do you see that?

2 A. I do.

3 Q. Do you understand that this
4 was foundational information for the
5 NWA's -- NWDA's suspicious order
6 monitoring system?

7 MR. WEINSTEIN: Objection to
8 form and foundation, and objection
9 to scope.

10 THE WITNESS: Again, I've --
11 I've not seen this document
12 before.

13 BY MR. PIFKO:

14 Q. Are you aware that your
15 website currently states that the NWA was
16 renamed the Healthcare Distribution
17 Management Association in 2001?

18 A. I am.

19 Q. Okay. So if these are from
20 the NWDA, they would have to be prior to
21 that date for sure, correct?

22 A. Yes.

23 Q. It's got a Section 2,
24 "Definition Of Suspicious Orders." It

1 says, "Suspicious orders include orders
2 of unusual size, orders deviating
3 substantially from a normal pattern, and
4 orders of unusual frequency."

5 Do you see that?

6 A. Yes.

7 Q. Is that consistent with what
8 your understanding of what is stated in
9 the regulations about the definition of
10 suspicious order?

11 A. That is all that is stated
12 in -- in the regulations, yes.

13 Q. I want to -- there's page
14 numbers on the bottom of this document,
15 Page 7, which is 02201916.

16 Tell me when you're there.

17 A. I'm there.

18 Q. Okay. It says, "Single
19 Suspicious Orders," Heading 9.

20 Do you see that, right
21 before summary?

22 A. I do.

23 Q. It says, "Single orders of
24 unusual size or deviation must be

1 reported immediately."

2 Do you see that?

3 A. I do.

4 Q. Is that consistent with your
5 understanding of what's required?

6 MR. WEINSTEIN: Objection to
7 form, foundation, and scope. And
8 calls for a legal conclusion.

9 THE WITNESS: Again, I see
10 what that -- it states. Again,
11 I'm not an attorney, so I don't
12 know what the individual practice
13 would require.

14 BY MR. PIFKO:

15 Q. Okay. Then it says here,
16 "The submission of a monthly printout of
17 after-the-fact sales will not relieve a
18 registrant from the responsibility of
19 reporting these single excessive or
20 suspicious orders."

21 Did I read that correctly?

22 A. You did.

23 Q. Then it says, "DEA has
24 interpreted 'orders'" -- the word orders

1 is in quotes -- "to mean prior to
2 shipment."

3 Do you see that?

4 A. I do.

5 Q. Did I read that correctly?

6 A. You did.

7 Q. So do you understand this to
8 be saying that an order has to be
9 identified before shipping it?

10 MR. WEINSTEIN: Objection to
11 form, foundation, scope. And
12 calls for a legal conclusion.

13 THE WITNESS: Again, I see
14 what it says here on paper. But
15 again I'm not an attorney. I'm
16 not exactly sure what the practice
17 would require.

18 BY MR. PIFKO:

19 Q. Okay. All I'm asking you is
20 what you understand this document to be
21 saying. You understand it to be saying
22 that an order needs to be identified and
23 reported prior to shipment.

24 MR. WEINSTEIN: Mark, he

1 said he's never seen this document
2 before.

3 THE WITNESS: I -- I can
4 read what -- what the document
5 says, yes.

6 BY MR. PIFKO:

7 Q. Is that -- is that what your
8 understanding of the document is? That's
9 all I'm asking.

10 MR. WEINSTEIN: Objection to
11 form. Objection to scope.

12 He's testified he's never
13 seen this document before. The
14 document says what it says.

15 THE WITNESS: Again, the
16 document says what it says and I
17 can read what it says.

18 BY MR. PIFKO:

19 Q. Okay. But you have English
20 comprehension. You understand when you
21 read something, right?

22 A. I -- I do have English
23 comprehension.

24 Q. Okay. So all I'm asking you

1 is what you understand this to be saying.

2 MR. WEINSTEIN: Same
3 objections.

4 THE WITNESS: I understand
5 it says, verbatim, DEA has
6 interpreted orders to mean prior
7 to shipment.

8 BY MR. PIFKO:

9 Q. Okay. And so do you
10 understand that to mean in the context of
11 this other language in the paragraph
12 here, that that means an order has to be
13 reported prior to being shipped?

14 MR. WEINSTEIN: Objection to
15 form, foundation, scope. And
16 calls for a legal conclusion.

17 THE WITNESS: Again, that's
18 what it says. That's what I would
19 understand it to mean.

20 BY MR. PIFKO:

21 Q. Okay.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-12.)

1 BY MR. PIFKO:

2 Q. I'm handing you what's
3 marked as Exhibit 12. It's a single page
4 e-mail. Bates labeled HDA_MDL_000150198.
5 Take a minute to review that and let me
6 know when you're done.

7 A. Okay.

8 Q. So this is from Anita Ducca
9 to Bill Wilson, who is the consultant who
10 is putting together the best practices or
11 industry compliance guidelines, correct?

12 A. Yes.

13 Q. Okay. And this is dated
14 January 10, 2008.

15 Do you see that?

16 A. Yes.

17 Q. She says, "Bill, all week we
18 have been contacting our members to
19 request their suspicious order
20 information."

21 Did I read that correctly?

22 A. You did.

23 Q. "This is the first of a few
24 e-mails I'll be sending with what we

1 received so far. This is from our member
2 Henry Schein, Inc."

3 Do you see that?

4 A. I do.

5 Q. So as we discussed, one of
6 the things that the consultant was
7 supposed to do was to obtain copies of
8 the member companies' suspicious order
9 policies and procedures and incorporate
10 information from those into these model
11 guidelines, correct?

12 MR. WEINSTEIN: Objection to
13 form.

14 MS. MACKAY: Objection to
15 form.

16 THE WITNESS: Correct, yes.

17 BY MR. PIFKO:

18 Q. Okay. So this confirms that
19 HDA was, in fact, collecting these
20 procedures and sending them to their
21 consultant, correct?

22 A. Yes, according to this, yes.

23 Q. Do you have any reason to
24 dispute that that happened?

1 A. I do not.

2 (Document marked for
3 identification as Exhibit
4 HDA-Kelly-13.)

5 BY MR. PIFKO:

6 Q. I'm handing you what's
7 marked as Exhibit 13. It's another
8 single page -- well, there's a tiny bit
9 of language on the second page.

10 MR. WEINSTEIN: And, Mark, I
11 should just say, to avoid any
12 confusion on the record, there's
13 obviously references throughout to
14 members. Mr. Kelly is obviously
15 interpreting that when you use
16 that phrase to mean the
17 distributor members.

18 If at any point you are
19 specifically referring to
20 manufacturer members, if you could
21 just make that clear, so that we
22 have a clear record, I would
23 appreciate that.

24 BY MR. PIFKO:

1 Q. Exhibit 13 is a document
2 Bates-labeled HDA_MDL_000139414 through
3 415.

4 MR. PIFKO: And, Brian, to
5 be clear, I understand that you're
6 trying to make your record, but
7 you can't be coaching the witness.
8 You can't be saying things like
9 he's never seen this before --

10 MR. WEINSTEIN: I absolutely
11 can --

12 MR. PIFKO: You can't be
13 saying things like --

14 MR. WEINSTEIN: -- when you
15 ask an inappropriate question.

16 MR. PIFKO: -- here -- here
17 is what the -- he's referring to.
18 You're not being deposed here.
19 Okay?

20 MR. WEINSTEIN: Mark, if you
21 ask an inappropriate question I'm
22 going to protect the record.

23 MR. PIFKO: You can -- you
24 can -- no --

1 MR. WEINSTEIN: So ask your
2 question --

3 MR. PIFKO: -- you can
4 object to form. You can object
5 for specificity --

6 MR. WEINSTEIN: I can object
7 when you ask an inappropriate
8 question.

9 MR. PIFKO: But you can't --
10 those are speaking objections --

11 MR. WEINSTEIN: Absolutely
12 not.

13 MR. PIFKO: -- and we're not
14 going to have those. Okay?

15 MR. WEINSTEIN: Absolutely
16 not. I'm very disciplined, and
17 I'll continue to act
18 appropriately.

19 BY MR. PIFKO:

20 Q. Let me know when you're done
21 reviewing this document.

22 A. Okay.

23 Q. So this is from Bill Wilson,
24 the consultant, e-mailing Ms. Ducca on

1 January 17, 2008.

2 Do you see that?

3 A. I do.

4 Q. The subject is "Rewrite."

5 And here he's sending a draft of the
6 questionnaire. You recall that that was
7 the first step of his engagement,
8 correct?

9 A. Yes.

10 Q. Okay. Do you have any
11 dispute -- any reason to dispute that
12 this is the first draft or one of the
13 drafts of his questionnaire that he was
14 going to be asking members when he
15 interviewed them?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: I have no
19 reason to dispute that this is the
20 first draft.

21 BY MR. PIFKO:

22 Q. Okay. And one of the topics
23 that he wants to ask HDMA's members is,
24 he says, "DEA says 'know your customer.'"

1 What is your understanding of that
2 statement and what as a company are you
3 doing to meet that requirement?"

4 Do you see that?

5 A. I do.

6 Q. Okay. Then there's a bunch
7 of questions. He has, "What steps do you
8 take about adding a new customer?"
9 Various questions about things people
10 could ask a new customer.

11 Do you see that?

12 A. I do.

13 Q. "How do you handle
14 discrepancies if they don't answer the
15 questions or if they leave something
16 blank?"

17 Do you see that?

18 A. No.

19 Q. Just below the block of
20 questions about adding a new customer.
21 "Based on information you gather from the
22 potential customer, how do you handle
23 discrepancies in the information" --

24 A. Okay. Okay. You -- all

1 right. Yes.

2 Q. That was something else that
3 he was asking?

4 MR. WEINSTEIN: Objection to
5 form.

6 BY MR. PIFKO:

7 Q. To the members, correct?

8 MR. WEINSTEIN: Same
9 objection.

10 THE WITNESS: Yes. Again,
11 this is the draft. So I don't
12 know what the actual final vehicle
13 entailed or not.

14 BY MR. PIFKO:

15 Q. Okay. One of the questions
16 is, "Do you feel what you are doing now
17 should be sufficient?"

18 Do you see that?

19 A. I do.

20 Q. You understand that that was
21 something that he was asking the members?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, whether

1 that was in the final. This is a
2 draft. And again, I don't know if
3 that was the final. I know that
4 was here on the paper, but first
5 draft.

6 BY MR. PIFKO:

7 Q. Okay. You understand Topic
8 4 is the guidelines and the process of --

9 A. Correct.

10 Q. -- gathering them, and that
11 is something that you're designated to
12 testify on about, right?

13 A. I do.

14 Q. And you have a duty to be
15 familiar with all the attributes of it,
16 correct?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: Of the
20 document -- yes. Of the ICGs,
21 yes, and the process.

22 BY MR. PIFKO:

23 Q. Okay. And the development
24 of them, correct?

1 A. Correct.

2 MR. WEINSTEIN: Objection to
3 form.

4 BY MR. PIFKO:

5 Q. This concerns developing
6 them, correct?

7 A. It does. I've not seen this
8 e-mail before.

9 Q. If you turn to the second
10 page. Two other questions here, "In
11 building a model for compliance, what
12 steps do you feel are essential to a good
13 compliance program?"

14 Do you see that?

15 A. I do.

16 Q. You understand that that was
17 something that was asked of HDA members
18 in connection with this project?

19 MR. WEINSTEIN: Objection to
20 form. Foundation.

21 THE WITNESS: Again, it was
22 part of the initial draft.

23 BY MR. PIFKO:

24 Q. How about, "In building a

1 model for compliance, what steps do you
2 feel you could not do based on your
3 customer base?"

4 Do you see that?

5 A. I do.

6 Q. You understand that that was
7 also something that was being discussed
8 with the members in connection with
9 drafting these guidelines?

10 MR. WEINSTEIN: Objection to
11 form. Foundation.

12 THE WITNESS: Again, I think
13 it was part of the first draft,
14 yes.

15 BY MR. PIFKO:

16 Q. You recall in some of the
17 other discussions that we looked at in
18 the prior exhibits, feasibility of the
19 guidelines and adaptability was a feature
20 that HDMA and its members wanted to
21 include in the guidelines, correct?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Correct.

1 BY MR. PIFKO:

2 Q. You didn't want to have
3 guidelines that its member companies
4 could not adopt, correct?

5 MR. WEINSTEIN: Objection to
6 form. Foundation.

7 THE WITNESS: Correct.

8 (Document marked for
9 identification as Exhibit
10 HDA-Kelly-14.)

11 BY MR. PIFKO:

12 Q. I'm handing you what's
13 marked Exhibit 14. For the record,
14 Exhibit 14 is a two-page document
15 Bates-labeled HDA_MDL_00213181 through
16 82. Take a minute to review it. Let me
17 know when you're done. It's another
18 e-mail from Ms. Ducca, two e-mails from
19 her, one dated Wednesday, February 6,
20 2008, and another one dated the same day,
21 just from an earlier time.

22 A. Okay.

23 Q. What do you know about Bill
24 Wilson's background?

1 A. I have never met Bill
2 Wilson. He was engaged during a time
3 before I got to the organization. I
4 understand that he was a consultant with
5 expertise in compliance-related issues.
6 I don't know if he had any specific DEA
7 experience or not.

8 Q. Looking at Exhibit 14, if
9 you -- you know how you read e-mails on
10 these. You have to read the back pages,
11 or the earlier pages.

12 So looking at the second
13 page, it's -- this e-mail Ms. Ducca
14 sends, Wednesday, February 6, 2008, and
15 the subject is HDMA RAC conference call
16 reminder.

17 RAC is regulatory affairs
18 committee, correct?

19 A. That's correct.

20 Q. And then it says here, "To
21 regulatory affairs committee.
22 Participants in the January 31 HDMA
23 meeting on suspicious order best
24 practices."

1 Do you see that?

2 A. I do.

3 Q. So there was going to be a
4 meeting on February 7th to discuss the
5 revised draft best practices, correct?

6 A. Yes.

7 Q. On the -- on the first page
8 of the e-mail she discusses a meeting
9 that occurred on January 31, 2008. If
10 you look at the attachments on the -- on
11 the header, it says, "Final slides for
12 1/31/08."

13 Do you see that?

14 HDMA. And then it also
15 says, "HDMA 01/31/08, D. Durkin."

16 Do you see that?

17 A. I do, yes.

18 Q. Okay. You recall that one
19 of the things in the discussions with the
20 consultant was that there was a deadline
21 of January 30th to get a draft of the
22 guidelines?

23 A. I -- I do recall that, yes.

24 Q. Okay. And you agree that

1 there was a meeting on January 31, 2008,
2 to discuss the guidelines and various
3 other aspects of it, of the project?

4 A. Yes.

5 Q. So looking at this first
6 page of the first e-mail, the top, the
7 more recent one, the second paragraph,
8 she says, "The meeting went very well and
9 we had excellent member input."

10 That's discussing the
11 January 31, 2008, meeting, correct?

12 A. Yes.

13 Q. "We discussed DEA's
14 requirements, expectations and recent
15 letters, and discussed the importance and
16 use of a set of best practices and what
17 the next steps will be after they are
18 completed."

19 Do you see that?

20 A. I do.

21 Q. Then she says, "I have
22 attached the overhead slides that HDMA
23 and our outside counsel provided at the
24 meeting. They go through what we said

1 about the above."

2 Do you see that?

3 A. I do.

4 Q. And then she says, "We also
5 reviewed a draft of best practices that
6 HDMA (a consultant and me) have put
7 together."

8 Do you see that?

9 A. I do.

10 Q. So Ms. Ducca and the
11 consultant worked together to put the
12 guidelines together?

13 A. Yes.

14 Q. And then they were discussed
15 with the member -- members at this
16 meeting, she says, based on input from
17 members at the meeting.

18 Do you see that?

19 A. I do.

20 Q. And then she says, "We
21 prepared a revised draft for additional
22 comment, and that revised draft is
23 attached."

24 Do you see that?

1 A. I do.

2 Q. Okay. And then, as we
3 discussed a moment ago, then there was
4 going to be another call on February 7th
5 to discuss the revised draft. Agree?

6 A. Yes.

7 Q. I'm going to hand you these
8 handouts from the January 31st meeting
9 starting with the first one which is
10 marked as Exhibit 15.

11 (Document marked for
12 identification as Exhibit
13 HDA-Kelly-15.)

14 BY MR. PIFKO:

15 Q. For the record, it's
16 Bates-labeled HDA_MDL_000213212 through
17 213228.

18 Let me know when you're
19 done. Again, take as much time as you
20 need to review the document, but I'm only
21 going to ask you about a couple slides.

22 A. Okay.

23 Q. Are you ready?

24 A. I am.

1 Q. Okay. The second -- the
2 first page of the Exhibit 15 is just a
3 cover page. The second page is the
4 agenda for the discussion.

5 Do you see that?

6 A. Yes.

7 Q. So review the antitrust and
8 antiharassment policies.

9 Then, background, DEA
10 suspicious order requirements. And
11 HDMA's best practices, the efforts to
12 date. Then legal and policy perspective.

13 Then there was going to be a
14 discussion about the potential best
15 practices, questions for attendees. And
16 then a discussion, allows for member
17 input. And then discussion of model
18 modifications, areas for further review.
19 And then a discussion of next steps,
20 additional DEA issues.

21 Do you see that?

22 A. I do.

23 Q. Do you agree that this was
24 the agenda of this portion of the -- the

1 meeting?

2 A. I do.

3 Q. I want to go to the fourth
4 page of the exhibit. It's got a little
5 bit of a timeline here. Let me know when
6 you're there.

7 A. I'm there.

8 Q. Okay. So it says, "Best
9 practices identified as a possible
10 solution."

11 This is the solution to the
12 increased DEA enforcement activity as we
13 discussed at the beginning of the
14 deposition, correct?

15 MR. WEINSTEIN: Objection to
16 form.

17 THE WITNESS: Yes.

18 BY MR. PIFKO:

19 Q. Okay. And so the best
20 practices was identified as a solution on
21 October 16, 2007, during an HDMA-DEA
22 meeting.

23 MR. WEINSTEIN: Objection to
24 form.

1 BY MR. PIFKO:

2 Q. Agree?

3 A. That's -- yeah, that's what
4 it says. Yes.

5 Q. Okay. And it's an HDMA
6 meeting regarding the DEA, right?

7 A. I believe it might have
8 been -- again, I'm not -- it was a --
9 either a meeting directly with DEA or
10 a -- if we -- is that on the timeline?

11 Q. That other meeting we talked
12 about with -- with --

13 A. Yeah, this was with DEA.

14 Q. Okay.

15 A. DEA participated in that
16 event.

17 Q. Okay. And then there was a
18 recommendation from outside counsel to
19 move forward on December 19, 2007, agree?

20 A. Yes.

21 Q. And then there was the
22 request for members' existing best
23 practices on January 3, 2008. Agree?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: Yes.

3 BY MR. PIFKO:

4 Q. And then the interviews and
5 follow-up requests occurred from
6 January 7th to January 11th. Agree?

7 A. Yes.

8 Q. And then there was a
9 presentation to the pain coalition on
10 January 1st, 2010 -- or, sorry,
11 January 10, 2008.

12 Do you see that?

13 A. I do.

14 Q. Do you have an understanding
15 as to why the -- there was a presentation
16 to the pain coalition about the best
17 practices for suspicious orders?

18 A. My understanding is that was
19 a monthly meeting, that group met fairly
20 regularly. And we went to apprise them
21 of the fact that we were developing the
22 guidelines for suspicious order
23 monitoring and reporting based on recent
24 DEA actions.

1 Q. The pain coalition, that's
2 the Pain Care Forum officially?

3 A. I believe it's one and the
4 same.

5 Q. Okay. And that includes
6 manufacturers in the pharmaceutical
7 industry, correct?

8 MS. MACKAY: Objection.
9 Foundation.

10 THE WITNESS: It includes --
11 my understanding, it includes a
12 variety of constituent groups in
13 the supply chain, including
14 patient groups, and manufacturers,
15 and distributors and pharmacies,
16 et cetera.

17 BY MR. PIFKO:

18 Q. Okay. But -- so all I'm
19 asking you is the Pain Care Forum
20 includes, among others, manufacturers in
21 the pharmaceutical industry, correct?

22 MS. MACKAY: Objection.
23 Foundation.

24 THE WITNESS: That's

1 correct.

2 BY MR. PIFKO:

3 Q. And the pain coalition, or
4 pain care foundation is specifically
5 focused on pain by its -- by definition,
6 correct?

7 MS. MACKAY: Objection --

8 MS. ROLLINS: Objection to
9 form.

10 MS. MACKAY: Objection.

11 Form. Foundation.

12 THE WITNESS: Again, the
13 Pain Care Forum -- Pain Care Forum
14 I think is the official name.

15 Again, issues and policies
16 related to the treatment of
17 individuals with pain, chronic
18 pain, terminal pain. Those types
19 of things.

20 BY MR. PIFKO:

21 Q. Treatment of pain?

22 MS. MACKAY: Objection.

23 Foundation. Form.

24 THE WITNESS: Treatment --

1 treatment of pain, yes.

2 BY MR. PIFKO:

3 Q. Pain advocacy?

4 MS. MACKAY: Same
5 objections.

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: Not so much
9 advocacy, more of just information
10 about policies that are being
11 discussed.

12 BY MR. PIFKO:

13 Q. And in connection with your
14 work for the HDA, have you attended a
15 Pain Care Forum meeting?

16 A. I personally have not.

17 Q. Have you discussed Pain Care
18 Forum meetings with your colleagues?

19 A. I am aware of past Pain Care
20 Forum meetings, yes.

21 Q. You are familiar with the
22 Pain Care Forum and its objectives and
23 its membership based on your role for the
24 HDA?

1 A. Again, generally, yes.

2 Not -- I couldn't name specific members
3 other than -- the top of my head.

4 Q. The HDMA is a member of the
5 Pain Care Forum, correct?

6 A. We are no longer a member of
7 the Pain Care Forum.

8 Q. But you were?

9 A. At one point we were.

10 Q. When did you stop being a
11 member of the Pain Care Forum?

12 A. I don't know the specific
13 date.

14 Q. In the last year?

15 A. Beyond that.

16 Q. Two years ago?

17 A. Again, I don't know the
18 specific date.

19 Q. Let's do this. When did you
20 join HDA?

21 A. 2011.

22 Q. Was HDA a member of the Pain
23 Care Forum when you first joined HDA?

24 A. I don't know for certain.

1 Q. Do you remember discussing
2 HDA ceasing to be a member of the Pain
3 Care Forum?

4 A. Vaguely.

5 Q. Who did you discuss that
6 with?

7 A. Again, one of the
8 discussions we have on an annual basis
9 about where we are -- have resources and
10 events and groups we're participating
11 with.

12 Q. Okay. In one of these
13 annual meetings you discussed the HDA's
14 involvement with the Pain Care Forum?

15 MS. MACKAY: Form.

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: Again, there
19 was a decision made -- I don't
20 know when -- to not participate
21 with the Pain Care Forum any
22 longer.

23 BY MR. PIFKO:

24 Q. Okay. Do you know what the

1 basis for that decision was?

2 A. Just general -- didn't have
3 staffing and resources to continue to
4 send people out to meetings and events.

5 Q. Okay. We'll come back to
6 that. Next slide, Page 5 of Exhibit 15.
7 Are you there?

8 A. Yes.

9 Q. It says the desired outcome
10 of the best practices, "Agree upon
11 fundamentals of distribution industry
12 best practices for suspicious orders for
13 government public policy committee
14 review. Eventually provide to DEA."

15 Do you see that?

16 A. I do.

17 Q. Did I read that correctly?

18 A. You did.

19 Q. Is that consistent with what
20 your understanding of the desired outcome
21 was?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Yes, at this

1 point in time, yes.

2 BY MR. PIFKO:

3 Q. Another goal of the meeting
4 and this ongoing discussion was to reach
5 agreement among HDA's members on these
6 best practices or guidelines, correct?

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: Yes.

10 BY MR. PIFKO:

11 Q. If you go to Page 7 of
12 Exhibit 15. It's got some bullet points
13 of attributes of the system. One of them
14 is, "Develop thresholds."

15 Do you see that?

16 A. Yes.

17 Q. It says, "Calculate average
18 orders for families."

19 Do you see that?

20 A. Yes.

21 Q. "ID orders of unusual size,
22 frequency, pattern"?

23 A. Yes.

24 Q. "And stop shipments"?

1 A. Yes.

2 Q. Those were all features of
3 the guidelines or best practices that you
4 were working on --

5 MR. WEINSTEIN: Objection.

6 BY MR. PIFKO:

7 Q. -- at this time?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: Yes. It's my
11 understanding.

12 BY MR. PIFKO:

13 Q. If you go to Page 8 of the
14 document. It talks -- there's another
15 attribute. It says "shipping" --
16 "shipment decisions."

17 Do you see that?

18 A. I do.

19 Q. Four decision options.

20 Do you see that?

21 A. I do.

22 Q. So you understood there was
23 going to be various options set out for
24 what someone could do when evaluating a

1 suspicious order as far as whether it
2 could be shipped?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Again, yes.

6 BY MR. PIFKO:

7 Q. I want to go to Page 12 of
8 the document.

9 So then, this discusses some
10 of the next steps. Ultimately there was
11 going to be a government public policy
12 committee review of the best practices or
13 guidelines on February 12th. Agree?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: Yes.

17 BY MR. PIFKO:

18 Q. Sorry, it's the government
19 public policy council, correct?

20 A. Correct.

21 Q. Okay. Then the executive
22 committee is going to review them on
23 February 22nd, correct?

24 A. Yes.

1 Q. And then you're going to
2 request a meeting with the acting DEA
3 administrator, correct?

4 A. Correct.

5 Q. And one question had was,
6 "Should the best practices become a
7 regulation?" Correct?

8 A. Correct.

9 Q. That was something that HDA
10 and its members were discussing?

11 A. Correct.

12 MS. MACKAY: Objection to
13 form.

14 BY MR. PIFKO:

15 Q. I'll direct you to Page 17
16 of Exhibit 15. Another thing that was
17 still being considered at this time was
18 whether HDA and its members would mount
19 to legal challenge to DEA, correct?

20 A. Yes.

21 Q. And then it says, "May
22 require extensive justification."

23 Do you see that?

24 A. Yes.

1 Q. "For example, DEA changed a
2 30-year reporting requirement to stopping
3 transactions."

4 Do you see that?

5 A. Yes.

6 Q. So one of the things that
7 HDA and its members were discussing at
8 this time in response to the DEA's
9 enforcement activity was to mount a legal
10 challenge concerning the reporting
11 requirement and whether it required
12 members to stop transactions?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: Yes.

16 (Document marked for
17 identification as Exhibit
18 HDA-Kelly-16.)

19 BY MR PIFKO:

20 Q. I'm handing you what's
21 marked as Exhibit 16. For the record,
22 this is another presentation from that
23 meeting. Bates-labeled HDA_MDL_000213229
24 through 213240.

1 One of the things referenced
2 in Ms. Ducca's e-mail, Exhibit 14, was
3 that she's attaching slides from HDMA and
4 the outside counsel.

5 This is the presentation
6 from HDMA's outside counsel at that
7 meeting. Please review it and let me
8 know when you're ready to discuss.

9 A. Okay.

10 Q. The discussion regarding the
11 industry compliance guidelines or best
12 practices was being facilitated through
13 the regulatory affairs committee; is that
14 correct?

15 MR. WEINSTEIN: Objection to
16 form.

17 THE WITNESS: Correct.

18 BY MR. PIFKO:

19 Q. Yes?

20 A. Yes.

21 Q. And again that included all
22 of HDA's distributor members, correct?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: The ones
2 that -- that participated, yes.

3 BY MR. PIFKO:

4 Q. And so those members would
5 have been part of the discussion on
6 January 31, 2008, where these were
7 presented, correct?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: The ones that
11 participated definitely, yes.

12 BY MR. PIFKO:

13 Q. And that included the big
14 three who participated, correct?

15 MS. ROLLINS: Objection to
16 form.

17 THE WITNESS: Again, I don't
18 have the exact list of
19 participants in front of me, but I
20 would imagine, yes.

21 BY MR. PIFKO:

22 Q. Because they're -- they're
23 on the regulatory affairs committee,
24 correct?

1 A. Yes.

2 Q. Trying to -- so again, as we
3 talked about when I handed you this
4 exhibit, this is from HDA's outside
5 counsel. It is a presentation entitled,
6 "Suspicious Orders and Diversion
7 Prevention," which was presented at the
8 meeting on January 31st in -- at HDA's
9 offices in Arlington, Virginia, correct?

10 A. That's my understanding,
11 yes.

12 Q. If you go to the third page
13 of the document, they are laying out the
14 statutory framework and conditions of
15 registration for -- do you see that here?

16 A. I do.

17 Q. Okay. The second bullet
18 point says, "The first factor in
19 determining the public interest is the
20 maintenance of effective controls against
21 diversion into other than legitimate
22 channels," correct?

23 MR. WEINSTEIN: Objection to
24 form. Foundation.

1 THE WITNESS: Yes. That's
2 what it says.

3 BY MR. PIFKO:

4 Q. If you go to the one with
5 the Bates number 213234 it says "Prior
6 Experience" on the top.

7 A. I see it.

8 Q. It says, under the heading
9 "Prior Experience," "DEA would not tell a
10 distributor if an order is legitimate or
11 not."

12 Do you see that?

13 A. Yes.

14 Q. And then it says, "DEA would
15 tell the distributor that it must decide
16 which orders are suspicious and make a
17 sales decision."

18 Do you see that?

19 A. Yes.

20 Q. The next slide has got some
21 criteria for suspicious orders.

22 Do you see that?

23 A. I do.

24 Q. Seven bullet points,

1 correct?

2 A. Yes, correct.

3 Q. And these aren't simply
4 repeating unusual size, pattern or
5 frequency, correct?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: It goes beyond
9 that.

10 BY MR. PIFKO:

11 Q. Right. It elaborates on
12 what that could mean, correct?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: That's what it
16 says, yes.

17 BY MR. PIFKO:

18 Q. Quantities of drugs
19 purchased, correct?

20 A. Correct.

21 Q. Percentage of controlled
22 versus noncontrolled, correct?

23 A. That's what it says, yes.

24 Q. Size of orders, correct?

1 A. Yes.

2 Q. Location of customer?

3 A. Yes.

4 Q. Different combinations of
5 drugs, correct?

6 MS. ROLLINS: Objection.

7 MS. MACKAY: Object to form.

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: It says only
11 phentermine, hydrocodone, and/or
12 alprazolam.

13 BY MR. PIFKO:

14 Q. Like if an order is only
15 those things, that potentially could be
16 suspicious. That's what it's saying
17 here?

18 MR. WEINSTEIN: Objection to
19 form. Foundation.

20 THE WITNESS: I imagine,
21 yes.

22 BY MR. PIFKO:

23 Q. No established business
24 credit, yes?

1 A. Yes. That's what it says.

2 Q. Frequent large orders,
3 correct?

4 A. Yes.

5 Q. Next slide is headed
6 "Issues."

7 Second bullet point, it
8 says, "Is the failure to report an
9 unusual order a violation if the drug is
10 dispensed for a lawful purpose?"

11 Do you see that?

12 A. Yes.

13 Q. So one of the things that
14 was discussed at this meeting was whether
15 it could still be a violation of the
16 regulations in the CSA if you didn't
17 report an unusual order even if it was
18 for a lawful purpose, correct?

19 A. Again, I think this one was
20 posited as a question.

21 Q. But my point is, that was
22 something that was being discussed.
23 Whether -- whether that would be a
24 violation or not, that was something

1 people were discussing at this meeting?

2 MR. WEINSTEIN: Objection to
3 form.

4 THE WITNESS: That's -- yes.

5 BY MR. PIFKO:

6 Q. Another thing discussed, if
7 you go to the slide, 000213238. Let me
8 know when you're there.

9 A. "What has changed?"

10 Q. Yes.

11 A. Yes.

12 Q. Second bullet point, it
13 says, "The suspicious nature of the order
14 depends not on pattern of ordering
15 customer, but on patterns of registrant's
16 customer base and patterns throughout the
17 regulated industry."

18 Do you see that?

19 A. I do.

20 Q. That was something else
21 discussed at this meeting?

22 A. It -- it was.

23 Q. Also that rigid formulas
24 were -- may be insufficient as well,

1 correct?

2 A. That was discussed.

3 (Document marked for
4 identification as Exhibit
5 HDA-Kelly-17.)

6 BY MR. PIFKO:

7 Q. Handing you what's marked as
8 Exhibit 17. For the record, it's an
9 e-mail with an attachment. Bates-labeled
10 HDA_MDL_000141125 through 141133. This
11 is an e-mail from Mr. Wilson dated
12 Tuesday, February 5, 2008, to Ms. Ducca,
13 attaching a discussion draft of the
14 interim -- industry compliance or best
15 practices guidelines.

16 Take a moment to review this
17 and let me know when you're ready.

18 A. Okay.

19 Q. Do you recall one of the
20 attributes of the scope of work that
21 Mr. Wilson was supposed to provide was to
22 draft -- put together an initial draft
23 and then potentially attend meetings and
24 do revisions, correct?

1 A. Yes.

2 Q. So he attaches this draft.

3 It says, "Discussion draft for meeting,"
4 as the file name. Do you see that on the
5 first page?

6 A. Yes.

7 Q. And then the following pages
8 are that discussion draft.

9 It says, "Discussion draft,
10 1/31/08."

11 Do you see that?

12 A. Yes.

13 Q. So this is the draft that
14 was discussed during that meeting,
15 correct?

16 A. Yes.

17 Q. So it's got several
18 features. Heading 1 is "Know Your
19 Customer."

20 Do you see that?

21 A. Yes.

22 Q. It says, "Before opening up
23 a new customer account, it is recommended
24 that the distributor obtain background

1 information on the customer and their
2 business, review the information for
3 discrepancies, and where appropriate,
4 verify the information."

5 Do you see that?

6 A. I do.

7 Q. And then it says, "The
8 following information is recommended,"
9 and it's got a whole host of information.

10 Do you see that?

11 A. Yeah. The following is
12 recommended -- yes, information gathered,
13 yes.

14 Q. Okay. At the bottom it
15 says, "Identify high purchasing doctors.
16 Also for pain clinics, identify high
17 writing doctors in the store's area."

18 Do you see that?

19 A. Right. And I -- what I
20 don't see here is that appears to be in a
21 different shade of font, whether that was
22 a note or that was part of -- it appears
23 that these are -- there are some notes
24 that are included. There's like the

1 draft document and then there are notes.

2 Q. Well, as we discussed, there
3 was a draft and then there was going to
4 be discussion. We know that from the
5 PowerPoints that we just went over as
6 Exhibits 15 and 16, that there was a
7 discussion of these during the meeting
8 with the members, correct?

9 A. Yes.

10 Q. Page 2 of the draft has got
11 some other information. "Questionnaires
12 must be update periodically especially
13 when new areas are developed for
14 investigation."

15 Do you see that?

16 A. I do.

17 Q. That's still under the
18 heading of "know your customer," correct?

19 A. Yeah, but it also appears to
20 be in a different font or a different
21 shade of font, so...

22 Q. Okay. "Whoever completes
23 the investigation must have documented
24 formalized training."

1 Do you see that?

2 A. I do see that.

3 Q. "Site visits should be
4 conducted when possible."

5 A. I see that, yes.

6 Q. Then it's got a Section 2
7 that is headed "Suspicious Order
8 Monitoring."

9 Do you see that?

10 A. I do.

11 Q. And then it's got a
12 background. It's got a citation to the
13 regulation.

14 Do you see that?

15 A. I do.

16 Q. And then it's got DEA
17 interpretations.

18 Do you see that?

19 A. I do.

20 Q. And move to the third page,
21 we see what those are, correct?

22 A. Yes.

23 Q. There's four discussion
24 points there, correct?

1 A. Yes.

2 Q. So one of them is, "DEA
3 distinguishes between an order and a
4 sale. Please note in the above cited
5 regulation there is no mention of a
6 sale."

7 Do you see that?

8 A. I do.

9 Q. Agree?

10 MR. WEINSTEIN: Objection to
11 form.

12 BY MR. PIFKO:

13 Q. That's what it says?

14 A. I agree that's what it says,
15 yes.

16 Q. "DEA believes that a
17 registrant should be able to determine if
18 an order meets the above description of
19 suspicious when they receive the order,
20 not when they ship it. This is
21 particularly true for orders of unusual
22 size."

23 Agree?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: That's what it
3 says, yes.

4 BY MR. PIFKO:

5 Q. Okay. "DEA has indicated
6 that cutting back on an order and
7 shipping less to avoid the suspicious
8 order definition (or to meet some
9 predetermined ship limit) does not
10 relieve distributors of the
11 responsibility of reporting the order as
12 fitting the suspicious order criteria."

13 Do you see that?

14 A. I do.

15 Q. And Item 4 says, "It is
16 likely that orders deviating
17 substantially from the normal pattern and
18 orders of unusual frequency will only be
19 'discovered by the registrant' after a
20 number of shipments have been made. DEA
21 expects shipments of such orders to be
22 stopped pending the outcome of an
23 investigation."

24 Do you see that?

1 A. I do see that.

2 Q. So you understood this as
3 documented here, were all DEA
4 interpretations of the regulation that's
5 cited above on Page 2 correct?

6 A. That's --

7 MS. ROLLINS: Object to the
8 form.

9 THE WITNESS: That's what I
10 understand.

11 BY MR. PIFKO:

12 Q. Then on Page 4, under that
13 same heading of suspicious order
14 monitoring, it's got another section,
15 "Develop 'thresholds' for suspicious
16 orders."

17 Do you see that?

18 A. I do.

19 Q. Okay. And then it's got a
20 discussion about how to calculate and
21 develop thresholds.

22 Do you see that?

23 A. Yes.

24 Q. Second paragraph says that,

1 "A threshold" -- it says, "Calculate the
2 average single order and the average
3 monthly order per family, per customer,
4 and class of trade. A minimum of six
5 months' sales history or a maximum of
6 24 months' sales history is recommended."

7 Do you see that?

8 A. I do.

9 Q. I read that correctly?

10 A. You did.

11 Q. So that's part of what is
12 being recommended for the development of
13 thresholds for suspicious orders,
14 correct?

15 MR. WEINSTEIN: Objection to
16 form.

17 THE WITNESS: In this draft,
18 yes.

19 BY MR. PIFKO:

20 Q. Okay. Then the next
21 paragraph says, "Also identify orders of
22 unusual size. It is recommended that
23 distributors follow past DEA criteria.
24 Specifically, DEA has recognized three

1 times the average for Schedule II
2 controlled substances and reportable
3 Schedule III orders as meeting the
4 unusual threshold."

5 Is that correct, that's what
6 it says?

7 A. Yes.

8 Q. You understand C-II means
9 Schedule II controlled substance,
10 correct?

11 A. I do.

12 Q. That was a feature of this
13 draft of the guidelines, correct?

14 A. Yes.

15 MS. WICHT: Object to the
16 form of the question.

17 BY MR. PIFKO:

18 Q. Then we have Heading 3,
19 "Investigation of suspicious orders,
20 shipment decisions."

21 Do you see that?

22 A. I do.

23 Q. First discussion point there
24 it says, "Should a distributor wish to

1 reconsider and ship an order identified
2 as potentially suspicious or part of such
3 an order, it is recommended that he or
4 she conduct an investigation to determine
5 the reasons for the order."

6 Did I read that correct?

7 A. You did.

8 Q. And that was part of the
9 discussion of investigation and shipping
10 of potentially suspicious orders,
11 correct?

12 A. Yes.

13 Q. Then it says, "Designating
14 an investigator."

15 Do you see that?

16 A. I do.

17 Q. And then it says -- I'm
18 paraphrasing -- that the person
19 designated should have suitable
20 experience and background to be able to
21 investigate potential suspicious orders.

22 Do you see that?

23 A. Yes.

24 Q. Then it talks about the

1 different elements of investigation on
2 Page 5.

3 Do you see that?

4 A. I do.

5 Q. One of them is to verify the
6 customer input.

7 Do you see that, at the
8 bottom of that section?

9 A. Yes.

10 Q. It says, "For example" -- it
11 says, "If the customer says they called
12 DEA, verify that they actually did so."

13 MR. WEINSTEIN: Objection to
14 form.

15 BY MR. PIFKO:

16 Q. Do you see that?

17 A. I do see that, yes.

18 Q. So verifying customer input
19 was an attribute -- an attribute of these
20 guidelines at this time, correct?

21 MS. ROLLINS: Form.

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: It says "where

1 appropriate" on the first line of
2 that. Yes, "Verify customer input
3 where appropriate. For example,"
4 and these are examples.

5 BY MR. PIFKO:

6 Q. And then there's -- at the
7 bottom of Page 5 it says, "Shipment
8 decisions. Decisions to ship an order
9 'of interest' should be made by a person
10 specifically authorized to conduct an
11 investigation and release the order."

12 Do you see that?

13 A. I do see that.

14 Q. Then it's got, on Page 6,
15 four decision options. Do you remember
16 when we looked at the slide deck from the
17 January 31st, 2008, meeting it talked
18 about the four decisions on shipment. Do
19 you remember that?

20 A. I do.

21 Q. And so here we have the four
22 decisions on shipment.

23 Do you see that?

24 A. I do.

1 Q. Okay. So one is cancel the
2 order and report; one is investigate,
3 cancel, and report; another one is
4 investigate and ship, don't report; and
5 the other one is investigate, ship, and
6 report. Agree?

7 A. That's what it says, yes.

8 Q. And then there is a note
9 here. "We need to define the point when
10 the order becomes suspicious."

11 Do you see that?

12 A. Yes.

13 Q. Then there is a question
14 here. It says, "Note: Do all of the
15 options above meet DEA's regulations?"

16 Number 3: "May be
17 inconsistent with the regulations, but
18 consistent with DEA's verbal guidance."

19 Do you see that?

20 A. I do.

21 Q. And that's saying
22 investigate and ship, but don't report,
23 correct, that's Number 3 is?

24 A. That's what Number 3 is,

1 yes.

2 Q. There's another section here
3 about filing reports with the DEA. It
4 talks about a month-end notification.
5 And then it says, "Delete this entire
6 section."

7 Agree?

8 A. That's what it says, yes.

9 Q. Okay. And as we read in the
10 other documents, an order needs to be
11 reported at the time it's identified as
12 being suspicious. That's consistent with
13 your understanding, correct?

14 MR. WEINSTEIN: Objection to
15 form, foundation, scope.

16 THE WITNESS: Again, I am
17 not sure where -- that's my
18 understanding of what they -- was
19 being discussed, yes.

20 BY MR. PIFKO:

21 Q. That is your understanding
22 of what was being discussed. I didn't
23 understand your answer.

24 A. So your question -- if you

1 would restate the question?

2 Q. Yeah, I was -- I was saying
3 if you remember, we looked at some of the
4 other documents and they talk about how
5 you need to report an order at the time
6 you identify it as suspicious. And this
7 is saying to delete the idea of a monthly
8 notification to DEA.

9 So you agree that that's
10 consistent with the idea that you need to
11 report it when you know it, correct?

12 MR. WEINSTEIN: Objection to
13 form, foundation, and scope.

14 THE WITNESS: Again, this
15 has to do with the -- the
16 notification to DEA, month -- on a
17 monthly basis. I'm not sure that
18 refers directly to the suspicious
19 order, per se.

20 BY MR. PIFKO:

21 Q. Well, it's under the heading
22 "File Suspicious Order Reports With the
23 DEA," Section 4.

24 Do you see that?

1 A. Right, but this has to do
2 with month-end DEA notification.

3 Q. Right. But it's saying to
4 delete the month-end. We're not going to
5 do that. Agree?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: I don't know
9 that we're not going to do that.
10 It just says delete that section.
11 I don't know what that -- what
12 that meant.

13 BY MR. PIFKO:

14 Q. Well, the section above
15 says, "Immediate DEA notification."

16 Do you see that?

17 A. I do see that.

18 Q. Okay. And then it's got a
19 section under there, it says, "DEA" -- it
20 says, "To meet the requirement," it says,
21 "When discovered."

22 Do you see that in quotes?

23 MS. CHARLES: Objection to
24 form.

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: Where -- which
4 section are you in?

5 BY MR. PIFKO:

6 Q. In the section --

7 A. Oh yes. In the top section,
8 yes.

9 Q. Do you see that?

10 A. "DEA office is recommending
11 to meet with the requirement to notify
12 when discovered unless DEA provides other
13 direction," yes.

14 Q. Let's go to Page 7. There
15 is a Heading 5, "Discussing Training and
16 Standard Operating Procedures."

17 Do you see that?

18 A. I do.

19 Q. And one of the things it
20 says there, at the bottom of that
21 training section is, "Training of
22 associates who are authorized to review,
23 stop, release an order, should be
24 extensive and there should be backup

1 training to cover the times when the
2 primary associate will not be available,
3 i.e., vacations, sick, et cetera?"

4 Did I read that correctly?

5 A. You did.

6 Q. And that was an attribute of
7 the -- these best practices or industry
8 compliance guidelines, correct?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: I will note --
12 I will note that this is in a
13 different font and I'm not sure if
14 this was part of the final
15 document or not.

16 BY MR. PIFKO:

17 Q. Okay. We'll get there.

18 And then it's got additional
19 recommendations.

20 "Note: Should we also
21 consider including any or all of the
22 following?"

23 Do you see that?

24 A. I do.

1 Q. So some of these other
2 things that are being considered are
3 whether periodic audits should be
4 conducted by the independent auditor,
5 correct?

6 A. That's what it says, yes.

7 Q. Should -- should the
8 industry support a customer accreditation
9 program?

10 A. Accreditation, yes.

11 Q. Identify an individual as a
12 DEA liaison for reporting suspicious
13 orders; is that correct?

14 A. That's what it says, yes.

15 Q. Retain a list of
16 questionable registrants. Maintain a
17 list of do-not-ship accounts.

18 Do you see that?

19 A. I do see that.

20 Q. That was something that was
21 being discussed as being included?

22 A. Again, different fonts. But
23 it's part of this document, yes.

24 Q. Have you seen the final

1 industry compliance guidelines?

2 A. Yes.

3 Q. So the document we just
4 discussed, Exhibit 17, it's just the
5 nitty-gritty, the details of the
6 guidelines, correct?

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: It's labeled
10 as a discussion draft.

11 BY MR. PIFKO:

12 Q. All I'm getting at is,
13 the -- the final draft has some
14 introductory explanatory language,
15 correct, the background about them,
16 correct, that's not in the discussion
17 draft, right?

18 A. Yes. There's addition --
19 and, again, I'm not sure what made it
20 from the discussion draft into the final
21 draft unless I was able to compare them
22 next to one another.

23 MS. CHARLES: Object to the
24 form of that question.

1 BY MR. PIFKO:

2 Q. I'm handing you what's
3 marked as Exhibit 18.

4 (Document marked for
5 identification as Exhibit
6 HDA-Kelly-18.)

7 BY MR. PIFKO:

8 Q. It's a three-page document,
9 Bates labeled HDA_MDL_000217851 through
10 853.

11 Just take a moment to review
12 this and let me know when you're done.

13 A. Okay.

14 Q. If you recall from
15 Exhibit 14, we talked about how the
16 consultant and Ms. Ducca worked on the
17 draft, correct?

18 A. Yes.

19 Q. And here in Exhibit 18,
20 Mr. Wilson, on February 6, 2008, is
21 sending her what he calls a discussion
22 intro, in the subject of the e-mail.

23 And he says, "Here is the
24 discussion header. I used the same

1 language you did on the draft. I will
2 call you tomorrow around 9:00 a.m. your
3 time."

4 Do you see that?

5 A. Yes.

6 Q. So he's sending her some
7 language that they discussed together,
8 agree?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: Again, yes.

12 BY MR. PIFKO:

13 Q. And so as we discussed,
14 the -- the final draft has some
15 background language, history, et cetera,
16 correct?

17 A. It does.

18 Q. Okay. And so this is a
19 first draft of that, it says, if you look
20 on the second page, first draft.

21 Do you see that?

22 A. I see that.

23 Q. And then it's got a heading
24 history. And it talks about 1970

1 Congress enacted the Controlled
2 Substances Act.

3 Do you see that?

4 A. Yes.

5 Q. Okay. At the bottom of that
6 page there's a section here, it says, "Up
7 until now, DEA has interpreted this
8 section to require distributors to design
9 and operate a system to identify and
10 report suspicious orders, based on the
11 regulation's definition of suspicious."

12 Did I read that correctly?

13 A. You did.

14 Q. The next page says,
15 "Recently, and without any due process
16 for rule changes, DEA has expanded the
17 definition of suspicious orders to
18 include those that the registrant may
19 have reason to believe the order will be
20 diverted."

21 Do you see that?

22 A. I do.

23 Q. Did I read that correctly?

24 A. You did.

1 Q. Then it says, "In three
2 public statements to congressional
3 committees on December 13, 2005; July 26,
4 2006; and September 18, 2007, the DEA
5 administrator has spoken about, quote,
6 the growing problem of diversion and
7 abuse of controlled pharmaceuticals
8 continues to be one of the top priorities
9 of the Drug Enforcement Administration."

10 "We have also used our
11 regulatory authority to take action
12 against DEA registrants found to be in
13 violation of regulatory requirements
14 under the Controlled Substance Act.

15 "Through regulatory
16 authority, DEA has subjected registrants
17 to significant civil fines, licensing
18 restrictions or even suspended
19 registration. Such civil remedies have
20 proven to be an effective deterrent to
21 potential violators."

22 Did I read that correctly?

23 A. You did.

24 Q. And then the last paragraph

1 says, "DEA seems to have taken the
2 position that if the registrant did not
3 know their customer was diverting,
4 they" -- in all caps -- "should have
5 known and have attached severe penalties
6 to not knowing. That is the purpose of
7 the following discussion points regarding
8 knowing your customer, identifying and
9 reporting suspicious order of controlled
10 substances, and training everyone who
11 comes into contact with controlled
12 substances."

13 Did I read that correctly?

14 A. You did.

15 Q. So at this time you agree
16 that it's saying the discussion points,
17 the attributes that we discussed in the
18 prior draft, those are all designed at
19 this idea of addressing the DEA's concern
20 that registrants should know if their
21 customers are diverting controlled
22 substances, correct?

23 MR. WEINSTEIN: Objection to
24 form, foundation, and scope.

1 THE WITNESS: That's
2 correct. That's what I understand
3 it to mean, yes.

4 (Document marked for
5 identification as Exhibit
6 HDA-Kelly-19.)

7 BY MR. PIFKO:

8 Q. I'm handing you what's
9 marked as Exhibit 19. This is another
10 e-mail from Ms. Ducca Bates-labeled
11 HDA_MDL_000148603 to 148633.

12 Take a moment to review it.
13 It attaches a revised draft of the
14 document we looked at in Exhibit 17.

15 MR. STEWART: Can we take a
16 break while he reads the document?

17 BY MR. PIFKO:

18 Q. I think he's done.

19 A. Yeah, I was trying to
20 determine what the -- so this is the
21 accepted changes versus --

22 Q. I'll walk you -- I'll walk
23 you through it here.

24 A. Okay.

1 Q. Okay. So if you'll recall
2 in Exhibit 14, Ms. Ducca talks about
3 scheduling call February 7th to have a
4 further discussion about the guidelines.

5 Do you see that? Or do you
6 recall that?

7 And then this Exhibit 19 is
8 her sending out attachments for this call
9 that's going to happen on February 7th,
10 agree?

11 A. Yes.

12 Q. And what we're seeing here
13 is a red line against the version that we
14 reviewed in Exhibit 17. That's actually
15 a clean version she attaches, and a red
16 line version. The red line starts at
17 148619, agree?

18 A. Yes.

19 Q. Okay. So then, you see this
20 draft, it's -- the heading on this draft
21 is Version 8, post 1/31/08. This is
22 distinguishing that it's after that
23 January 31, 2008, meeting, correct?

24 A. Yes.

1 Q. And now this draft has some
2 of the introductory background language
3 that we discussed in Exhibit 18, correct?

4 A. Yes, with the addition of
5 some additional information.

6 Q. Right. So not all of the
7 language that we discussed in Exhibit 18
8 made it into this draft, correct?

9 A. That's -- yes, from what I
10 could tell.

11 Q. For example, there was that
12 paragraph, "Up until now DEA has
13 interpreted this section that required
14 distributors to design and operate a
15 system to identify and report suspicious
16 orders."

17 Do you remember that
18 discussion? That's not in here, correct?

19 A. What -- what version are you
20 looking at?

21 Q. If you have -- if you want
22 to open Exhibit 18 up --

23 A. Okay. I'm sorry.

24 Q. -- and compare it to what

1 you're seeing in the introduction and
2 history section in Exhibit 19. That
3 paragraph is not in there, correct?

4 A. It does not appear to be.

5 Q. And then the section,
6 "Recently, without any due process for
7 rule changes," that whole paragraph in
8 Exhibit 18 isn't in here either, correct?
9 It's not in Exhibit 19, correct?

10 A. It does not appear to be.

11 Q. Okay. And so let's look at
12 some of the language that's added here
13 from the January 31st, 2008, draft that
14 we reviewed in Exhibit 17.

15 First, in the introduction.
16 Let me know when you're there.

17 A. We're on the second --

18 Q. If you want to use the red
19 line, you can, which starts on 148619.

20 A. Okay.

21 Q. Are you there?

22 A. I -- yes.

23 Q. This allows us to see what's
24 added from the prior draft that was in

1 Exhibit 17, agree?

2 A. Yes.

3 Q. And so all of this language,
4 the introduction, history, distribution
5 industry, commitment to securing the
6 supply of controlled substances, that's
7 all new, correct?

8 A. From the version in 17?

9 Q. Yeah.

10 A. Exhibit 17? Yes.

11 Q. Okay. And so one of the
12 things in the first paragraph, it says,
13 is that, at the bottom of that first full
14 paragraph, it's talking about these
15 guidelines. It says, "They have been
16 prepared in recognition of the growing
17 problem of misuse of controlled
18 substances and the key role distributors
19 play within the prescription drug supply
20 chain."

21 Did I read that correctly?

22 A. You did.

23 Q. Okay. And so is that
24 consistent with what your understanding

1 of the background of how these were
2 prepared?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Yes, that's
6 what I understand it to be.

7 BY MR. PIFKO:

8 Q. And HDMA and its members
9 recognized that there was a growing
10 problem of misuse of controlled
11 substances at this time?

12 MR. WEINSTEIN: Objection to
13 form. Foundation. Scope.

14 THE WITNESS: That's what we
15 stated here in this introduction.

16 BY MR. PIFKO:

17 Q. And the role -- and the key
18 role that distributors play within the
19 prescription drug supply chain, correct?

20 MR. WEINSTEIN: Same
21 objections.

22 THE WITNESS: Again, it's
23 stated here in the introduction.

24 BY MR. PIFKO:

1 Q. And then in the next
2 paragraph it says, "While drug wholesale
3 distributors, like all nongovernmental
4 entities, do not have investigative
5 powers and resources to guarantee that
6 certain products will not reach illicit
7 or illegal markets, they are uniquely
8 situated to perform due diligence in
9 order to help support the security of the
10 controlled substances distribution
11 system."

12 Did I read that correctly?

13 A. You did.

14 Q. That was another thing that
15 HDA and its members recognized at this
16 time, correct?

17 MR. WEINSTEIN: Objection to
18 form. Foundation. Scope.

19 THE WITNESS: And included
20 it in this introduction, yes.

21 BY MR. PIFKO:

22 Q. It then says, "Rigorous" --
23 in the next paragraph, "Rigorous due
24 diligence can aid in providing a greater

1 level of assurance that those who
2 purchase controlled substances from
3 wholesale distributors intend them to be
4 used for legitimate and legally
5 acceptable patient needs."

6 Did I read that correctly?

7 A. You did.

8 Q. "In other words, with such
9 due diligence, it is possible to reduce
10 the probability that controlled
11 substances will reach locations within
12 the supply chain for which they are not
13 intended."

14 Did I read that correctly?

15 A. You did.

16 Q. And so HDMA and its members
17 recognized this to be true at this time
18 as well, correct?

19 MR. WEINSTEIN: Objection to
20 form, foundation, scope.

21 THE WITNESS: It's what's
22 stipulated here in this
23 introduction, yes.

24 BY MR. PIFKO:

1 Q. So let's go to the second
2 page. There's a heading, "Distribution
3 Industry Commitment to Securing the
4 Supply of Controlled Substances."

5 Do you see that?

6 A. I do.

7 Q. It says in that paragraph,
8 partway through the first sentence,
9 "Recent concerns about the potential
10 misuse of controlled substances has
11 elevated their awareness and that of the
12 DEA and the public, to the need for
13 greater rigor in evaluating the purchase
14 orders of such" -- "for such products."

15 Did I read that correctly?

16 A. Yes.

17 MS. MACKAY: Object to the
18 form.

19 BY MR. PIFKO:

20 Q. And the HDA and its members
21 understood that to be true at this time,
22 correct?

23 MR. WEINSTEIN: Objection to
24 form, foundation, and scope.

1 THE WITNESS: That's what's
2 stated here in this document, yes.

3 BY MR. PIFKO:

4 Q. Then in the next paragraph
5 it says, second sentence, "We are
6 confident that implementation of these
7 guidelines will aid in the appropriate
8 distribution of controlled substances to
9 supply chain partners involved in the
10 legitimate dispensing of these important
11 products to patients they serve."

12 Did I read that correctly?

13 A. You did.

14 Q. And HDMA and its members
15 understood that to be true at this time,
16 correct?

17 MR. CRAWFORD: Objection to
18 form.

19 MR. WEINSTEIN: Objection to
20 form, foundation, and scope.

21 THE WITNESS: They
22 understood that -- that these were
23 guidelines that could help in
24 addressing prescription drug

1 diversion, yes.

2 BY MR. PIFKO:

3 Q. And HDMA and its members put
4 this -- this language together, correct?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: HDMA and its
8 distributor members, yes.

9 BY MR. PIFKO:

10 Q. And all the language we've
11 been discussing, correct?

12 MR. WEINSTEIN: Objection to
13 form.

14 MS. MACKAY: Foundation.

15 THE WITNESS: Yes, the
16 language that is before us, that
17 we're looking at is prepared by
18 HDMA and HDMA member companies,
19 distributor member companies.

20 BY MR. PIFKO:

21 Q. There's another section a
22 few pages in, "Stop Shipments of an Order
23 of Interest."

24 Let me know when you're

1 there.

2 A. Page 7? I'm there.

3 Q. Yeah, okay. And it's got
4 two options.

5 Do you see that?

6 A. I do.

7 Q. And it's talking about
8 whether, if there's a suspicious order, a
9 distributor should stop the whole order
10 or they could ship a portion of the
11 order. Do you agree that's what it's
12 discussing.

13 MS. ROLLINS: Object to the
14 form.

15 THE WITNESS: Where -- where
16 are you reading?

17 BY MR. PIFKO:

18 Q. Well, there's two options
19 Option 1 stop shipments of the individual
20 drug code product that is an order of
21 interest.

22 A. I see that, yes.

23 Q. Or then it's saying
24 Option 2: "Distributors may ship a

1 portion of the entire individual drug
2 code product that is an order of
3 interest."

4 Do you see that?

5 A. I do see that, yes.

6 Q. So there was a discussion at
7 this time as to which of those options
8 was going to be included in this -- into
9 the final draft, correct?

10 MS. CHARLES: Objection to
11 form.

12 THE WITNESS: I don't
13 know -- I don't know what the
14 intention was for including the
15 options, if that was a discussion
16 about including one or the other
17 or leaving both.

18 MR. WEINSTEIN: Mark, we've
19 been going about an hour and a
20 half. If there's a good point
21 for --

22 MR. PIFKO: Yeah, let me
23 just hand him this exhibit. I'm
24 just going to address that topic

1 and then we can take a break.

2 MR. WEINSTEIN: A few more
3 minutes?

4 THE WITNESS: Yep.

5 (Document marked for
6 identification as Exhibit
7 HDA-Kelly-20.)

8 BY MR. PIFKO:

9 Q. I'm handing you what's
10 marked as Exhibit 20. For the record,
11 it's a document Bates-labeled
12 HDA_MDL_000213058 through 213077. It's a
13 PowerPoint from the HDA government public
14 policy council dated February 12, 2008,
15 titled, "HDMA-DEA Suspicious Orders 'best
16 Practices.'"

17 Let me know when you are
18 ready.

19 A. Okay.

20 Q. So you recall when we first
21 discussed the hiring of Mr. Wilson and
22 the decision that HDMA was going to put
23 out these best practices, that ultimately
24 they have to get approved by the board,

1 correct?

2 A. That's correct.

3 Q. And so this is a meeting
4 that's discussing getting to --
5 ultimately getting to approval of the
6 guidelines, correct?

7 A. Correct.

8 Q. And we see on the second
9 page it says agree -- "Goals: Agree upon
10 final draft of best practices for
11 executive committee review."

12 Do you see that?

13 A. Yes.

14 Q. And then it says, "Resolve
15 partial shipment issue."

16 Do you see that?

17 A. Yes.

18 Q. And that's the issue we were
19 discussing in Exhibit 19 where there's
20 the two options. Agree?

21 MS. CHARLES: Objection to
22 form.

23 THE WITNESS: Yes.

24 BY MR. PIFKO:

1 Q. Then we see a calendar on
2 Slide 3 that's got the different events.
3 This is consistent with what we've been
4 discussing and your understanding of the
5 process, correct?

6 There was a meeting on
7 January 31, 2008, and we looked at --
8 Exhibit 19 was the revised draft provided
9 to the regulatory affairs committee on
10 February 7th for them to review. Here
11 it's got the 8th.

12 And then this is -- this
13 meeting on February 12, 2008, for the
14 government public policy council to
15 review?

16 A. Yes.

17 Q. Agree?

18 A. Yes.

19 Q. Some of these slides are
20 similar to the presentation we saw on --
21 on January 31st that we went over on
22 Exhibit 16, correct?

23 MS. CHARLES: Object to the
24 form.

1 THE WITNESS: Yeah, I
2 don't -- I don't believe there was
3 a timeline, but yes, similar in
4 scope. Yes.

5 BY MR. PIFKO:

6 Q. Discussion of legal -- yeah,
7 there's like just legal discussions about
8 the requirements and the Rannazzisi
9 letters. Agree?

10 A. Agree.

11 MS. ROLLINS: Objection to
12 form.

13 BY MR. PIFKO:

14 Q. Okay. So then I want to
15 direct your attention to Slide 11, it's a
16 slide headed "Next Steps."

17 Do you see that?

18 A. I do.

19 Q. So second bullet point --
20 well, first bullet point is that the
21 executive committee is going to review
22 them on February 22nd, agree?

23 A. Yes.

24 Q. And then another next step

1 is that we're going to continue pharmacy
2 association/pain coalition discussions,
3 agree?

4 A. That's what it says, yes.

5 Q. And so there was going to be
6 an effort to continue discussing these
7 with the Pain Care Foundation as we
8 discussed before, correct?

9 MR. WEINSTEIN: Objection to
10 form.

11 MS. CHARLES: Objection to
12 form.

13 MR. WEINSTEIN: Foundation.

14 THE WITNESS: That's what it
15 says, yes.

16 BY MR. PIFKO:

17 Q. Do you have any reason to
18 dispute that it happened?

19 A. I do not.

20 Q. Then another next step is
21 going to request a meeting with the DEA
22 acting administrator. You recall that we
23 discussed that when we first looked at
24 the scope of work for this, correct?

1 A. Yes.

2 Q. And then one point of
3 discussion was to request DEA endorsement
4 of the best practices as a safe harbor.

5 Do you see that?

6 A. I do.

7 Q. You understood that there
8 was going to be a request to the DEA that
9 if people implemented these, they would
10 have a safe harbor with respect to
11 diversion control compliance?

12 MS. MACKAY: Objection to
13 form.

14 THE WITNESS: Again, I
15 think -- I think -- yeah, the
16 concept was to basically broach
17 these as a potential solution to
18 due diligence under the
19 expectations of DEA. I don't know
20 if we officially requested their
21 endorsement. We did show them the
22 completed guidelines.

23 BY MR. PIFKO:

24 Q. In addition to due

1 diligence, know your customer and not
2 shipping suspicious orders, correct?

3 MR. WEINSTEIN: Objection to
4 form.

5 MS. ROLLINS: Objection to
6 form.

7 THE WITNESS: I'm sorry.
8 With --

9 BY MR. PIFKO:

10 Q. With respect to -- you said,
11 "The concept was basically to broach
12 these as a potential solution to due
13 diligence." But I'm saying, also know
14 your customer and the idea of not
15 shipping suspicious orders, correct?

16 A. Right. That would all be
17 included in due diligence, yes.

18 Q. Okay. Slide 16. It's got
19 some key points from the January 31st
20 meeting. Are you there?

21 A. I am.

22 Q. Okay. First one is -- it
23 says that, "Implementing the best
24 practices will expand distributors'

1 efforts considerably." And considerably
2 is in italics.

3 Do you see that?

4 A. I do.

5 Q. Okay. So if you were going
6 to implement these, it would be a
7 considerable effort, correct?

8 MR. WEINSTEIN: Objection to
9 form. Foundation.

10 THE WITNESS: It would be --
11 yes. That's what I understand it
12 to mean.

13 BY MR. PIFKO:

14 Q. And then it says,
15 "Inevitably impacts customers, may be
16 significant."

17 Do you see that?

18 A. I do see that.

19 Q. So there could be a
20 significant impact on customers from
21 implementing these, correct?

22 MR. WEINSTEIN: Objection to
23 form. Foundation. Scope.

24 THE WITNESS: That's what I

1 understand it to mean, yes.

2 BY MR. PIFKO:

3 Q. And go to Slide 17. This is
4 a discussion of that partial shipment
5 option that we looked at that was in the
6 draft in Exhibit 19, agree?

7 A. Yes.

8 Q. And so it's got some -- it
9 identifies the issue of what should be
10 done. And then it's got voting, agree?

11 MS. CHARLES: Objection to
12 form.

13 THE WITNESS: That's, I
14 guess, what it appears to have.
15 I'm not sure if that's voting
16 within the regulatory affairs
17 committee.

18 BY MR. PIFKO:

19 Q. But there's some voting, by
20 some constituent within HDA, correct?

21 A. This appears to indicate
22 that, yes.

23 MS. CHARLES: Objection to
24 form.

1 BY MR. PIFKO:

2 Q. And it says, "If a specific
3 drug code product order is potentially
4 suspicious, should the distributor be
5 able to ship part of the order for that
6 particular product prior to further
7 evaluation?"

8 That's what it says,
9 correct?

10 A. That's what it says, yes.

11 Q. And then it says seven are
12 in favor, three opposed, one abstained,
13 and one was absent, agree?

14 A. That's what it says.

15 MR. WEINSTEIN: Objection to
16 form.

17 BY MR. PIFKO:

18 Q. And then it's got pros and
19 cons of adopting that approach, agree?

20 A. That's what it lists, yes.

21 Q. One of the pros is it's
22 consistent with the current practice for
23 many distributors, agree?

24 MR. WEINSTEIN: Objection to

1 form. Foundation.

2 THE WITNESS: That's what it
3 says, yes.

4 BY MR. PIFKO:

5 Q. A con is that DEA
6 correspondence/interpretation is do not
7 support this practice, agree?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: That's what it
11 says, yes.

12 MR. PIFKO: We can take a
13 break.

14 THE VIDEOGRAPHER: The time
15 is 12:06 p.m. We are going off
16 the record.

17 - - -

18 (Lunch break.)

19 - - -

20 A F T E R N O O N S E S S I O N

21 - - -

22 THE VIDEOGRAPHER: The time
23 is 12:44 p.m. We are back on the
24 record.

1 - - -

2 EXAMINATION (Cont'd.)

3 - - -

4 BY MR. PIFKO:

5 Q. I'm handing you what's
6 marked as Exhibit 21.

7 (Document marked for
8 identification as Exhibit
9 HDA-Kelly-21.)

10 BY MR. PIFKO:

11 Q. It's another series of
12 e-mails from Anita Ducca dated March 4th,
13 2008, attaching another version of the
14 guidelines, Bates-labeled
15 CAH_MDL2804_01521412 through 1469.

16 There's another red line of
17 this draft against the draft that we
18 looked at in Exhibit 19. I'm not going
19 to ask you any questions about it. But
20 you can review it. But in the interest
21 of time, I was just want to direct your
22 attention to the first page of
23 Exhibit 21.

24 A. That's all we're going to

1 be?

2 Q. Yeah.

3 A. Do you want me to read the
4 back end of it?

5 Q. Sure. I'm not going to ask
6 you about that either. Just the e-mail
7 on the front.

8 A. I've read the top sheet.

9 Q. Okay. So Exhibit 21 is
10 Anita Ducca sending to the regulatory
11 affairs committee members another draft
12 of the suspicious orders best practices,
13 agree?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: Yes. I think
17 that's -- that's what it entails.
18 And with kind of a changing of the
19 name to the practice guidelines,
20 which was not the final name of
21 the document, but...

22 BY MR. PIFKO:

23 Q. Right, so she says, "I've
24 attached a copy of the very latest

1 version of the draft suspicious order
2 practices. The executive committee
3 approved these."

4 Do you see that?

5 A. Yes.

6 Q. The executive committee
7 approved the draft she attaches in this
8 document, correct?

9 A. That's what I understand it
10 to mean, yes.

11 Q. And then it says, "Also, we
12 have made some changes, mostly regarding
13 wording and formatting and included
14 recommendations by our outside counsel
15 and our communications department,
16 including a suggestion to re-name them
17 'recommended practice guidelines.'"

18 Do you see that?

19 A. I do.

20 Q. So the outside counsel or
21 communications department recommended
22 that you re-name them?

23 A. Again, I don't know who
24 recommended exactly renaming them. I do

1 know that they were vetted with various
2 external groups to determine how they
3 should be named and packaged and
4 presented.

5 Q. Do you know what other
6 external groups?

7 A. Other than -- I mean,
8 external groups as far as within the
9 organization. So our government affairs
10 committees, our communications
11 committees, legal counsel, outside
12 counsel.

13 Q. And so this says, "Change
14 them to recommended practice guidelines,"
15 but ultimately they ended up being called
16 industry compliance guidelines, correct?

17 A. Correct.

18 Q. Do you know if there were
19 any other iterations of what they would
20 be called in between this and the final
21 name?

22 A. I -- I do not know. I
23 think -- again, I think the practice -- I
24 mean I think we wanted to stay away from

1 basically establishing anything that said
2 best practices or standards because we
3 are not a standard setting organization.

4 We can't compel our members
5 to, you know, adopt these best practices,
6 per se. So they are guidelines. They
7 are voluntary guidelines.

8 Q. So then, this also talks
9 about how there's going to be a meeting
10 with Mark Caverly. He's from the DEA,
11 correct?

12 A. Correct.

13 Q. And again, this is
14 consistent with the overall strategy that
15 we saw in the earlier documents that was
16 designed in 2007 where you're going to
17 draft these, get industry to all agree on
18 the language, and then have a meeting
19 with DEA to discuss them, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: Again, get
23 our -- get our members that were
24 participating in that process to

1 agree on them. And then basically
2 vet them with the DEA to see if
3 they had any concerns with the
4 scope of the -- of the guidelines.

5 (Document marked for
6 identification as Exhibit
7 HDA-Kelly-22.)

8 BY MR. PIFKO:

9 Q. I'm handing you what's
10 marked as Exhibit 22. It's an e-mail
11 from HDA's Kristen Freitas dated
12 Thursday, March 20, 2008. Due to some
13 sort of way the document was produced,
14 there's a lot of gibberish and blank
15 pages, but the substance can be distilled
16 down to four pages.

17 But for the record, it's
18 Bates-labeled ANDA_OPIOIDS_MDL_0000157358
19 to 157473.

20 For the record, take a
21 minute to review it and let me know when
22 you're done.

23 The substantive discussion
24 starts at 157380, it ends at 83. I think

1 that's where you were.

2 A. 8383?

3 Q. Yeah.

4 A. 157383? Okay.

5 Q. So my first question is, who
6 is Kristen Freitas?

7 A. Kristen Freitas is currently
8 now the vice president of federal
9 government affairs for HDA, then HDMA.
10 She was then probably a manager or a
11 director.

12 Q. It says here on her
13 signature on the second page, associate
14 director.

15 A. Associate director.

16 Q. What's federal government
17 affairs do?

18 A. Federal government affairs
19 is tasked primarily with the interface
20 with Congress. The HDA segment of the
21 government affairs department that deals
22 directly with Congress, anything that
23 happens on the Hill.

24 Q. Is that a -- something

1 that's under your purview in your current
2 position?

3 A. It is.

4 Q. Okay. So Kristen Freitas
5 reports to you?

6 A. Up through me, yes. I'm the
7 head of the department. She reports
8 directly to our general counsel.

9 Q. Okay. So at this time,
10 she's talking about some other aspects of
11 the strategy to, as we talked about in
12 Exhibit 3, address the executive
13 committee's concerns about recent DEA
14 activities to involve wholesale
15 distributors in efforts to prevent
16 diversion. Agree?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: I'm sorry. So
20 you -- you --

21 BY MR. PIFKO:

22 Q. This is a furtherance of the
23 overall strategy that we talked about
24 that was starting to be implemented in

1 Exhibit 3, which derives from the
2 executive committee's concerns about
3 recent DEA activities to involve
4 wholesale distributors in efforts to
5 prevent diversion. Do you agree?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: That should --
9 yes. I would agree it is part of
10 that process.

11 BY MR. PIFKO:

12 Q. Okay. So then she says
13 here, "DEA - as we discussed on the
14 federal government affairs committee call
15 on Monday, HDMA staff have developed a
16 confidential draft political strategy to
17 address some of the issues related to DEA
18 and suspicious orders. As the document
19 states, many of the tactics and messaging
20 hinge on the outcome of the DEA meeting
21 where we will" -- "we will present our
22 recommended industry compliance
23 guideline."

24 Did I read that correctly?

1 A. You did.

2 Q. Okay. So it was understood
3 within HDA and its members that,
4 depending on this meeting where the
5 guidelines were shared with the DEA, that
6 would shape how further strategies were
7 implemented, agree?

8 MR. WEINSTEIN: Objection to
9 form. Foundation.

10 THE WITNESS: I would agree,
11 yes.

12 BY MR. PIFKO:

13 Q. So then we see, if you go to
14 157380, there's a discussion of various
15 tactics that are going to be part of "the
16 HDMA Hill DEA strategy."

17 Do you see that?

18 A. I do.

19 Q. Okay. Tactic Number 1 is,
20 "Complete and present recommended
21 industry compliance guidelines to DEA
22 general counsel."

23 Do you see that?

24 A. Yes.

1 Q. Okay. You agree that's the
2 first tactic mentioned here?

3 A. That is, yes.

4 Q. And then it says, "Status:
5 Request to be made the week of
6 March 17th."

7 Agree?

8 A. That's what it says, yes.

9 Q. And like we just saw in the
10 prior department, "The discussion and
11 outcome of this meeting will be critical
12 in driving all further tactics and
13 messaging."

14 Agree?

15 A. That's what it says, yes.

16 Q. Then it says, "Brief House
17 appropriation subcommittee members who
18 participated in the March 12th DEA budget
19 justification hearing. Seek questions to
20 be asked for the record."

21 Do you see that?

22 A. Yes.

23 Q. Do you have an understanding
24 about what that was about?

1 A. Again, I think it had to do
2 with, and the timing of this would have
3 been -- if this is after the -- the
4 hearing. This was on March 20th.

5 Again, I think it was
6 basically when FDA or DEA on an annual
7 basis goes before the appropriation
8 committee to discuss their budget, that
9 if there were concerns or questions about
10 their perspective on our guidelines or
11 their suspicious order monitoring
12 tactics, that we provide some feedback to
13 the appropriation members so they could
14 ask for further clarification from the
15 administrator while she was there
16 testifying.

17 Q. Okay. And so you drafted,
18 on behalf of your members, potential
19 questions to be asked by members of
20 Congress to ask the DEA, correct?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: That's what I
24 understand these to be, yes.

1 BY MR. PIFKO:

2 Q. And that starts on 157382
3 and goes to 383, correct?

4 A. Correct.

5 Q. Okay. Tactic 3 is, "Brief
6 Senate appropriation subcommittee members
7 in advance of DEA budget justification
8 hearing. Seek commitment to ask
9 questions of DEA administrator."

10 Do you see that?

11 A. Yes.

12 Q. Do you have an understanding
13 what that's about?

14 A. Again, similar to what was
15 done on the House side. But again maybe
16 those questions were developed for the
17 Senate side, because it appears that this
18 e-mail was sent after the 3/12
19 appropriations committee.

20 Q. Okay. So these questions
21 are for senators to ask the DEA?

22 A. I would deduce that
23 that's -- yes, that's the process.

24 Q. And that's a common tactic

1 that you use in the organization, is to
2 draft questions for senators or members
3 of Congress to ask DEA if you have
4 concerns?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: That is a
8 common practice for a lot of
9 associations that interact with
10 regulatory authorities.

11 BY MR. PIFKO:

12 Q. Including HDA?

13 A. In this instance including
14 HDA.

15 Q. And so when it says, "Brief
16 senate appropriation subcommittees in
17 advance of the hearing," there's also
18 one-on-one meetings that occur with the
19 senators in advance of the hearing?

20 MR. WEINSTEIN: Objection to
21 form. Foundation.

22 THE WITNESS: I would
23 imagine these are primarily
24 meetings with staff,

1 staff-to-staff meetings. Seldom
2 to the member representatives
3 participate in those meetings. So
4 these are staff briefings.

5 BY MR. PIFKO:

6 Q. That's where the questions
7 are provided?

8 MR. WEINSTEIN: Objection to
9 form. Foundation.

10 THE WITNESS: Again, that's
11 where I -- if they were provided,
12 again, I don't know what was
13 provided. This was looking at a
14 draft document of some kind. I am
15 not sure which specific questions
16 were provided or if any of the
17 questions were provided.

18 BY MR. PIFKO:

19 Q. Okay. But in your ordinary
20 practice as part of your lobbying
21 efforts, that's how questions would be
22 provided, you would have your staff
23 members meet with lawmakers' staff
24 members and that's when you would discuss

1 your views and provide potential
2 questions?

3 A. Correct.

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: Sorry.

7 BY MR. PIFKO:

8 Q. Go a few more tactics down.
9 Number 6, it says, "Educate and seek
10 advocates for HDMA among pain community
11 who will assist in delivering our message
12 to Hill."

13 Do you see that?

14 A. I do.

15 Q. So you were going to, as
16 part of this effort, you were going to
17 also enlist others in the pain community
18 to communicate your message to lawmakers;
19 that's correct?

20 MS. CHARLES: Objection to
21 form.

22 THE WITNESS: That's what
23 this indicates.

24 BY MR. PIFKO:

1 Q. And then it says, "Status,
2 HDMA joined and briefed the Pain Care
3 Forum, an informal coalition of
4 pharmaceutical companies and patient
5 advocacy groups focusing on pain
6 management issues and will follow up upon
7 release of our industry compliance
8 guidelines."

9 Did I read that correctly?

10 A. You did.

11 Q. Okay. And so that confirms
12 HDMA did join the Pain Care Forum,
13 correct?

14 A. Yes. In 2008.

15 Q. And you briefed them on
16 these issues, correct?

17 MS. MACKAY: Objection to
18 form.

19 THE WITNESS: Again, this
20 seems to indicate that we briefed
21 them that we were developing the
22 industry compliance guidelines
23 just to give them a heads-up. And
24 we were indicating to this, we

1 would share our final document
2 when it was developed and
3 released.

4 BY MR. PIFKO:

5 Q. And then you sought their
6 contribution to also advocate to members
7 on the Hill, correct?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: Again I don't
11 know what the specific ask was.
12 This was an informal kind of
13 coalition group, and we were
14 briefing them on what we were
15 doing. This seems to indicate
16 that we were -- educate and seek
17 advocates for HDMA among pain
18 community who will assist in
19 delivering our message on the
20 Hill. So yes, it appears that we
21 were asking them to support our
22 industry compliance guidelines.

23 BY MR. PIFKO:

24 Q. And then Number 8 says,

1 "Identify high-level congressional
2 'champion' who will request a meeting
3 with DEA to discuss concerns with current
4 tactics."

5 Do you see that?

6 A. I do.

7 Q. Do you have an understanding
8 about what that's about?

9 A. Again, what it says. So
10 probably ask a member of Congress,
11 possibly a high-level senior ranking
12 official or a ranking member in their
13 party to request a meeting with DEA,
14 possibly a committee chairman of some
15 kind, a relevant committee.

16 Q. And so at this time HDMA and
17 its members were concerned with the
18 enforcement tactics being used by the
19 DEA, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: I think -- I
23 think there was concern about the
24 lack of clarity and basically what

1 we were trying to basically convey
2 in some of the questions that were
3 put together. So we were -- yeah,
4 we were seeking greater clarity
5 from the agency and it was not
6 forthcoming, and so we were
7 requesting that our congressional
8 colleagues possibly request a
9 meeting so we could convey those
10 concerns.

11 BY MR. PIFKO:

12 Q. When I handed you this
13 document, you read it in its entirety,
14 correct?

15 A. The document that I'm
16 looking at right now?

17 Q. Yeah. We took a moment and
18 you were reading it?

19 A. Yeah, I read -- yes, the
20 pages that you referenced, yes.

21 Q. You read the questions --
22 potential Hill questions for DEA, right?

23 A. I did, yes.

24 Q. Okay. And so the thrust of

1 the questions, you know, goes at the end
2 here. It says, if you look on 157382,
3 "Isn't your initiative overly broad and
4 not focused specifically enough on rogue
5 pharmacies, which in fact make up a
6 miniscule percentage of any legitimate
7 wholesaler's business?"

8 And then it says, "Clearly,
9 if a customer is known to be diverting
10 prescription drugs and the wholesale
11 distributor continues to supply that
12 customer, a violation of their registrant
13 responsibilities as has occurred. But my
14 concern here is that your expectations go
15 to a much higher level, asking the
16 wholesaler in essence to be your
17 investigator. I don't think that's
18 appropriate. It seems to me at the end
19 of the day that prescription drug abuse
20 is caused by inappropriate prescribing
21 and inappropriate dispensing, neither of
22 which wholesalers are authorized or
23 capable of regulating or enforcing."

24 Do you see that?

1 A. I do.

2 Q. That's a question that you
3 wanted a senator to ask the acting
4 administrator of the DEA, correct?

5 A. It was -- it was developed
6 here. Again, I don't know if it was ever
7 requested, a senator or staff or anybody.

8 Q. But at this stage it's a
9 potential question for some lawmaker to
10 ask the DEA, correct?

11 A. That's -- yes. That's the
12 context for this.

13 (Document marked for
14 identification as Exhibit
15 HDA-Kelly-23.)

16 BY MR. PIFKO:

17 Q. I'm handing you what's
18 marked Exhibit 23. If you recall,
19 earlier on in Exhibit 8, there was an
20 e-mail from Anita Ducca that attached
21 some of her draft summaries of the
22 various meetings and events that occurred
23 in connection with the industry
24 compliance guidelines and meetings with

1 the DEA. And this is -- Exhibit 23, is
2 one of those attachments. She said, if
3 you recall, these were draft summaries of
4 her meetings.

5 A. Yes.

6 Q. Okay. So take a minute to
7 look at Exhibit 23, and -- which is a
8 three-page document, and let me know when
9 you're done. For the record, the Bates
10 labels are CAH_MDL2804_02489188 through
11 190.

12 A. Okay.

13 Q. So this is a summary of the
14 first meeting that HDA had with DEA
15 concerning the industry compliance
16 guidelines, correct?

17 A. That's correct.

18 Q. It identifies that attendees
19 here from DEA and from HDMA, correct?

20 A. It does.

21 Q. And in addition to HDMA
22 members, it also identifies Richard
23 Cooper from Williams & Connolly as an
24 attendee and David Durkin from Olsson

1 Frank law firm as well?

2 A. It does, yes.

3 Q. And who is Robert Barnett,
4 is he -- is he from Williams & Connolly
5 as well?

6 A. Yes.

7 Q. Okay. They were outside
8 counsel to HDA at this time?

9 A. Yes.

10 Q. Along with David Durkin?

11 A. That's correct.

12 Q. Okay. And so Anita Ducca is
13 there, and Scott Melville, who was your
14 predecessor was there?

15 A. Yes.

16 Q. So Ms. Ducca has a meeting
17 summary here. So it appears that Bob
18 Barnett and Rich Cooper led the
19 introductory remarks in the meeting,
20 agree?

21 A. Yes. They led off.

22 Q. Okay. So, Bob explained the
23 purpose of the meeting. He explained --
24 I'm reading from the document -- "the

1 serious concerns among HDMA members
2 regarding DEA's recent actions regarding
3 suspicious orders. When HDMA first
4 contacted Williams & Connolly regarding
5 possibly challenging DEA, Bob and Rich
6 Cooper recommended an alternative that
7 was based on his prior experience with
8 other clients in similar positions."

9 Do you see that?

10 A. I do.

11 Q. Did I read that correctly?

12 A. You did.

13 Q. Do you recall that being
14 part of the discussion, that when HDMA
15 first came to Williams & Connolly to
16 potentially challenge DEA, they came up
17 with an alternative idea?

18 A. Again, I was not at HDA at
19 the time. But I understand from reading
20 this, reviewing this document, that was
21 the -- that was the initial part of the
22 discussion.

23 Q. And so Williams & Connolly
24 recommended that, instead of challenging

1 the DEA, that the distributors develop a
2 set of business practices of their own
3 or, as this says, "a type of standard as
4 a better approach to show DEA to the
5 outside world what is intended" -- "that
6 they intend to be part of the solution
7 rather than problem"; is that correct?

8 A. That's correct. Those were
9 his words, yes.

10 Q. And that's what he told DEA
11 at this meeting?

12 A. I will take it at face value
13 that that's what was explained, yes.

14 Q. Other points that Bob
15 Barnett made were that "HDMA hoped that
16 DEA would find the guidelines acceptable
17 as a voluntary 'consent decree,' and we
18 hoped to receive some form of imprimatur
19 from you."

20 Agree?

21 A. That's what it says, yes.

22 Q. It's noted here, Bob also
23 told DEA, "These guidelines have been
24 adopted and approved by HDMA's board."

1 Agree?

2 A. Which bullet point are you
3 on?

4 Q. Second to last on the first
5 page.

6 A. Yes.

7 Q. But then it was explained
8 that HDMA and its board were open to
9 suggestions from the DEA, correct?

10 A. That's correct.

11 Q. And then it says, "If DEA
12 accepted them, you wanted to make some
13 sort of public statement about it,"
14 correct?

15 A. That's -- yes, that's what
16 it -- that's what it says, yes.

17 Q. So -- then, we're going to
18 the second page here. So it says, "After
19 Bob's introductory discussion, he turned
20 the meeting over to Richard Cooper from
21 Williams & Connolly."

22 Agree?

23 A. Yes.

24 Q. Okay. And so Rich is the

1 one who had this previous experience with
2 the FDA where they developed standards
3 that were voluntary and eventually became
4 standard practice among the medical
5 research community, and this idea of the
6 industry compliance guidelines was born
7 out of that, agree?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: I think that's
11 what's being implied here, yes.

12 BY MR. PIFKO:

13 Q. And that's what was told to
14 DEA in connection with this meeting,
15 correct?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: That's --
19 again, that's what it -- seems to
20 be stipulated here, yes.

21 BY MR. PIFKO:

22 Q. So a key point, according to
23 Anita's notes is that Rich Cooper from
24 Williams & Connolly made, was that "an

1 order and question will be stopped until
2 there was an assessment and found that
3 the order was not suspicious."

4 Agree?

5 A. Where --

6 Q. Second paragraph, full
7 paragraph of Page 2.

8 A. Okay. Yes. I see that,
9 yes.

10 Q. And so then, DEA had a
11 question about "what exactly are you
12 stopping when you stop the order?"

13 A. Okay.

14 Q. And that's some discussion
15 about that.

16 Do you see that?

17 A. Yes.

18 Q. And so then, Rich Cooper
19 told DEA that "the guidelines indicated
20 that the entire order of the specific
21 product that triggered the threshold
22 should be held and not released."

23 Do you see that?

24 A. Yes.

1 Q. And then he also said, "The
2 guidelines expected that the entire order
3 for the drug product in question would be
4 held, even if part of it came under a
5 threshold."

6 Do you see that?

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: Yes. Last
10 sentence.

11 BY MR. PIFKO:

12 Q. Okay. And so that resolves
13 this partial shipment issue we discussed
14 before the break, agree?

15 MS. ROLLINS: Objection to
16 form.

17 THE WITNESS: Again, it
18 seems to indicate that there
19 was -- yes, that was going to be
20 the final recommendation in the --
21 in the guidelines.

22 BY MR. PIFKO:

23 Q. To pull the entire -- entire
24 order while the drug in question was

1 investigated, correct?

2 MR. WEINSTEIN: Objection to
3 form.

4 THE WITNESS: Again, I think
5 that's, yes, what this seems to
6 entail.

7 BY MR. PIFKO:

8 Q. So then the meeting was
9 handed over to Scott Melville, your --
10 your predecessor, agree?

11 A. Yes.

12 Q. And Scott told the DEA that,
13 if you look in those bullet points, that
14 "HDMA and its members intended to help
15 implement the guidelines by making
16 consultants known to them who could aid
17 in the implementation."

18 Do you see that?

19 A. I do.

20 Q. And then he said that "they
21 would discuss it with the Pain Care
22 Forum"?

23 A. Yes.

24 Q. And that "HDMA would hold

1 webinars and seminars to educate the
2 members and the customers about the
3 guidelines as well"?

4 A. Yes.

5 Q. And Scott also told DEA that
6 "HDA would discuss, explain and encourage
7 acceptance of the guidelines by other
8 trade associations, including
9 manufacturing and pharmacy groups."

10 That's the second bullet
11 point on the page?

12 A. Yes, yes, yes, yes, yes.

13 Q. So you agree, a key message
14 that Scott was communicating to DEA here
15 was that HDA was going to work to make
16 sure its members and other participants
17 in the supply chain in the pharmaceutical
18 industry would implement these
19 guidelines, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: I think we --
23 we meant to basically educate the
24 rest, that they were available.

1 Again, we are not a
2 standards agency, we are not a
3 regulatory authority. We can't
4 basically make any entity comply
5 with the guidelines. We were just
6 going to educate as many folks as
7 we could about their existence and
8 make them available.

9 BY MR. PIFKO:

10 Q. But you told DEA that you
11 wanted to help your members implement the
12 guidelines, correct?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: That's -- yes,
16 that's what it -- that's what it
17 says here, yes.

18 BY MR. PIFKO:

19 Q. Handing you what's marked as
20 Exhibit 24.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-24.)

24 BY MR. PIFKO:

1 Q. It is a three-page e-mail
2 between HDA and AmerisourceBergen.
3 Bates-labeled HDA_MDL_000156499 through
4 156501.

5 Take a minute to review
6 this, and let me know when you're done.

7 There is some discussion
8 about whether Chris Zimmerman from
9 AmerisourceBergen is going to serve as
10 a -- a chairman of a committee. I'm not
11 interested in that part of the discussion
12 here.

13 A. Okay.

14 Q. This goes back to earlier in
15 the process of developing the industry
16 compliance guidelines or best practices,
17 agree, it's back in early January 2008?

18 A. Yes.

19 Q. And this is before this
20 meeting with DEA, correct?

21 A. It is.

22 Q. Okay. And in this e-mail on
23 the first page, 156499, Mr. Zimmerman
24 tells HDA's Anita Ducca, "I think we need

1 to discuss the suspicious order project.
2 Since ABC has an agreement with DEA, it
3 does not matter what best practices HDMA
4 develops because ABC must adhere to its
5 written agreement with DEA. I assume
6 Cardinal will be in the same boat.
7 Therefore, I'm not sure what benefit ABC
8 would receive from this project."

9 Do you see that?

10 A. I do.

11 Q. Did I read that correctly?

12 A. You do.

13 Q. Okay. So you agree that at
14 this time Mr. Zimmerman is saying that
15 he's not going to implement any
16 guidelines or best practices, and he
17 assumes Cardinal is not going to either,
18 correct?

19 MS. ROLLINS: Object to
20 form.

21 MR. WEINSTEIN: Objection to
22 form. Foundation.

23 THE WITNESS: I think what
24 he's implying is that they are

1 already under strict adherence to
2 a specific plan with -- directly
3 with the DEA that satisfies their
4 obligations. But it's specific to
5 those companies individually,
6 therefore, a model plan or
7 guidelines is irrelevant for them.

8 BY MR. PIFKO:

9 Q. And they have no plan on
10 implementing them at this time, correct?

11 MS. ROLLINS: Objection to
12 form.

13 MR. WEINSTEIN: Objection to
14 foundation and form.

15 THE WITNESS: Because they
16 have their own policies in place.

17 BY MR. PIFKO:

18 Q. You said here that they have
19 a plan that satisfies the DEA. Where
20 does it say that it satisfies the DEA?

21 A. I'm deducing from this
22 document that since ABC has an agreement
23 with DEA, it does not matter what best
24 practices HDMA develops because ABC must

1 adhere to its written agreement with DEA.

2 Q. What about Cardinal?

3 MR. WEINSTEIN: Objection to
4 form.

5 MS. CHARLES: Objection to
6 form.

7 BY MR. PIFKO:

8 Q. It doesn't say anything like
9 that about Cardinal, does it?

10 MR. WEINSTEIN: Objection to
11 form. Foundation.

12 THE WITNESS: An individual
13 from ABC insinuates that Cardinal
14 may be a similar position due to
15 a -- maybe a consent decree that
16 Cardinal entered into with DEA as
17 well that would be in the same
18 constriction with regard to their
19 practices that ABC is at the time.

20 BY MR. PIFKO:

21 Q. And so the HDA knew this
22 information before it had the meeting
23 with DEA, correct?

24 A. Obviously we were apprised

1 that they were basically not going to be
2 of help in developing the guidelines or
3 adopting the guidelines, because they are
4 there are under a separate agreement.

5 Q. Do you know if
6 AmerisourceBergen ever asked DEA if it
7 could follow the guidelines as an
8 improvement on measures it was already
9 engaged in?

10 MS. ROLLINS: Objection to
11 form.

12 MR. WEINSTEIN: Objection to
13 form. Foundation.

14 THE WITNESS: I do not.

15 BY MR. PIFKO:

16 Q. No one ever told you that
17 they had requested anything from DEA as
18 far as being able to implement the
19 industry compliance guidelines?

20 MS. ROLLINS: Objection to
21 form.

22 THE WITNESS: That ABC had
23 requested? Again, I don't know.

24

1 BY MR. PIFKO:

2 Q. Same question about Cardinal
3 Health.

4 MS. CHARLES: Objection to
5 form.

6 THE WITNESS: Again I don't
7 know. I don't know.

8 BY MR. PIFKO:

9 Q. To your knowledge, did any
10 distributor implement the industry
11 compliance guidelines?

12 MR. WEINSTEIN: Objection to
13 form. Foundation.

14 THE WITNESS: Again, I don't
15 know. They were -- they were
16 guidelines. Many of the
17 companies, from what I understand,
18 already had various processes in
19 place. These guidelines were
20 developed to better inform them
21 about expectations within the DEA.
22 And if they -- they could beg and
23 borrow, and again it was meant to
24 be kind of something that could be

1 applicable to various size
2 companies and be able to adapt.

3 So again I don't know if
4 anybody adopted the entire
5 document verbatim or not. And we
6 didn't ask.

7 BY MR. PIFKO:

8 Q. You don't know if anybody
9 adopted parts of the document either,
10 correct?

11 MR. WEINSTEIN: Objection to
12 form.

13 THE WITNESS: We don't.

14 BY MR. PIFKO:

15 Q. So sitting here today, you
16 don't know, and at no time does HDMA know
17 if any members or other distributors
18 adopted all or part of the industry
19 compliance guidelines, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: I don't know,
23 nor did we ask. And again, I
24 stated before, we are not a

1 regulatory authority; we are not a
2 standard-setting body. We are
3 simply doing our best to inform
4 our members about existing
5 policies.

6 BY MR. PIFKO:

7 Q. And to your knowledge, no
8 pharmaceutical manufacturer ever adopted
9 the industry compliance guidelines or any
10 portion of them, correct?

11 MR. WEINSTEIN: Objection to
12 form.

13 MS. MACKAY: And foundation.

14 THE WITNESS: And again,
15 they were not -- they were not
16 developed for manufacturers. They
17 were developed for our core
18 members, the distributor members
19 of HDA.

20 BY MR. PIFKO:

21 Q. But you did discuss them
22 with the Pain Care Forum, which included
23 manufacturers, correct?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: Among many
3 other groups, yes. A lot of
4 pharmacies groups, everybody in
5 the supply chain.

6 BY MR. PIFKO:

7 Q. Okay. And just to be
8 clear -- I think you had the answer, but
9 I don't think we have a clear record.

10 To your knowledge, no
11 distributor, manufacturer, or pharmacy
12 has ever implemented the guidelines or
13 any portion of the guidelines, correct?

14 MR. WEINSTEIN: Objection to
15 form. Foundation.

16 THE WITNESS: Again, I think
17 every distributor member has their
18 own compliance guidelines that are
19 basically developed and put in
20 place for their company, their
21 specific customer base, et cetera.
22 I don't know that anybody kind of
23 copied the industry compliance
24 guidelines and made it part of

1 their own protocols and
2 procedures. I don't know. Nor
3 did we ask.

4 BY MR. PIFKO:

5 Q. I want to turn your
6 attention back to Exhibit 2. Are you
7 there?

8 A. Yes. I'm at Exhibit 2.

9 Q. You want you to go to the
10 page Bates-labeled HDA_MDL_000081366.
11 It's got dates that start with
12 September 30, 2010, to March 2011.

13 Do you see that?

14 A. Yes.

15 Q. So on February 25, 2011, it
16 says, "ExComm concurs with government
17 policy" -- government public policy
18 council directive. Requests review of
19 consistency between the ICG and member
20 practices."

21 Do you see that?

22 A. Yes.

23 Q. So HDA did review the
24 consistency of member practices with the

1 ICG --

2 MR. WEINSTEIN: Objection to
3 form.

4 BY MR. PIFKO:

5 Q. -- in February 25th, 2011?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: No. I think
9 what we asked was, were the ICGs
10 still relevant. That was -- we
11 wanted to make sure that our
12 guidelines were still
13 relatively -- we weren't asking
14 whether they were consistent with
15 our -- with basically our
16 guidance. Were our guidelines
17 still relevant and consistent four
18 years of their publication or
19 three years after the publication.

20 BY MR. PIFKO:

21 Q. Well, no, it says -- it
22 literally says in the document, "Request
23 review of consistency between the ICG and
24 member practices."

1 A. Is the ICG current.

2 Q. Right. But there's a -- you
3 were reviewing whether there was
4 consistency between the member practices
5 and the ICG, correct?

6 MR. WEINSTEIN: Are you
7 testifying for the witness or is
8 there a question in there?

9 MR. PIFKO: I'm asking him a
10 question.

11 THE WITNESS: Again -- and,
12 again, this is just as a statement
13 in a -- in a chronology here. I
14 think the -- the request was to
15 basically look at the ICGs and
16 determine based on what they are
17 doing and what's confronting them
18 in that marketplace, at that time,
19 three years after the publication,
20 are they still relevant and are
21 they still current.

22 BY MR. PIFKO:

23 Q. Right. But there's a
24 comparison of the ICGs and the member

1 practices at that time, correct?

2 MR. WEINSTEIN: Objection to
3 form.

4 THE WITNESS: That we
5 requested the individual member
6 companies to look at our ICGs and
7 compare them with their practices,
8 and let us know if they were still
9 relevant.

10 We did not review individual
11 company member practices. And nor
12 could we with our antitrust.

13 BY MR. PIFKO:

14 Q. Well, you did. You
15 requested the -- the member companies'
16 practices when you developed the industry
17 compliance guidelines. You've already
18 testified to that, it's all over the
19 documents.

20 A. We -- we submitted -- we
21 submitted a questionnaire. We asked them
22 to respond to the questionnaire based on
23 what their practices were. And again we
24 didn't -- we didn't ask for their

1 practices verbatim.

2 Q. You did --

3 A. To the extent that they were
4 comfortable --

5 Q. Ms. Ducca expressly said she
6 would facilitate that with the
7 consultant. Are you now --

8 MR. WEINSTEIN: Objection to
9 form.

10 BY MR. PIFKO:

11 Q. -- disputing what you said
12 on the record before?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: No. That --

16 MR. WEINSTEIN:

17 Mischaracterizes testimony.

18 THE WITNESS: I'm not --

19 I'm -- I'm not disputing that at
20 all.

21 The consultant was brought
22 in, developed a questionnaire.
23 The questionnaire was submitted to
24 the membership. Those that felt

1 comfortable responding to the
2 questionnaire, did.

3 We did not ask for their
4 policies. We asked them to
5 respond to the questionnaire. To
6 some extent, it --

7 BY MR. PIFKO:

8 Q. That's -- that's not --
9 that's not what the document says. And
10 that's not what you testified to earlier.

11 MR. WEINSTEIN: Objection to
12 form. Wait for a question.

13 BY MR. PIFKO:

14 Q. Remember, that we are under
15 oath here?

16 A. I do.

17 MR. WEINSTEIN: Sir, come
18 on, Mark, give me a break.

19 MR. PIFKO: He's trying to
20 change his testimony.

21 MR. WEINSTEIN: Give me a
22 break, Mark. Ask your questions.

23 BY MR. PIFKO:

24 Q. Exhibit 10 talks about the

1 processes that the consultant's going to
2 use, and it says, "Obtaining where
3 available copies of HDMA member
4 companies' internal suspicious order
5 business practices." And Anita Ducca
6 said she was going to handle that.

7 And then in Exhibit 12, she
8 says, "We've been contacting our members
9 to request their suspicious order
10 information. This is the first of a few
11 e-mails I'll be sending you." She sends
12 the policies from Henry Schein. It's
13 separate than the -- the interview
14 questionnaire that was discussed.

15 MR. WEINSTEIN: Just wait
16 for the question.

17 BY MR. PIFKO:

18 Q. So are you disputing that
19 HDA requested copies of its members'
20 suspicious order practices?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: I'm not -- I'm
24 not disputing what was -- what was

1 typed. I'm not aware that we were
2 receiving verbatim copies of their
3 suspicious order monitoring
4 protocols.

5 BY MR. PIFKO:

6 Q. That was expressly part of
7 the protocol.

8 MR. WEINSTEIN: Objection to
9 form.

10 BY MR. PIFKO:

11 Q. Are you disputing that?

12 MR. WEINSTEIN: Objection to
13 form.

14 THE WITNESS: Again, are you
15 referencing a specific --

16 BY MR. PIFKO:

17 Q. Yeah. Exhibit 10 --

18 A. Exhibit 10.

19 Q. It says she is going to
20 review the members' suspicious order
21 policies.

22 A. This is in the -- where are
23 you referring to?

24 Q. Page 2.

1 MR. WEINSTEIN: Of
2 Exhibit 10.

3 MR. PIFKO: 3(B).

4 THE WITNESS: Where
5 available copies of HDMA member
6 copies --

7 BY MR. PIFKO:

8 Q. "Obtaining where available
9 copies of HDMA member companies' internal
10 suspicious business order practices."

11 Then if you look at Page 3
12 she says, "Contacting HDMA members to, A,
13 request copies of their current
14 suspicious orders business practices.
15 HDMA can facilitate this by sending an
16 e-mail to our members making the
17 request."

18 That's different from the
19 interviews. C is the interviews.

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: Again --

23 BY MR. PIFKO:

24 Q. In Exhibit 12 she sends Bill

1 stuff from Henry Schein and says she is
2 sending others. So --

3 MR. WEINSTEIN: Objection to
4 form.

5 BY MR. PIFKO:

6 Q. -- are you disputing that
7 HDA collected suspicious order practices
8 from its members?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: I'm not
12 disputing that.

13 BY MR. PIFKO:

14 Q. Okay. That's all I'm
15 asking.

16 A. Again, I don't know what
17 attachments were submitted by Henry
18 Schein.

19 Q. I'm handing you what's
20 marked as Exhibit 25.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-25.)

24 BY MR. PIFKO:

1 Q. Exhibit 25 is a document
2 Bates-labeled HDA_MDL_000213079 through
3 213088. It's a document, PowerPoint
4 presentation entitled, "DEA Suspicious
5 Orders: Recommended Industry Compliance
6 Guidelines. Regional round table. May
7 7, 2008."

8 Take a minute to review
9 this, and let me know when you're done.

10 A. Okay.

11 Q. Do you know who this
12 presentation was made to?

13 A. From what I understand, this
14 was before I joined the organization.
15 There were a series of briefings that we
16 would provide to members that weren't
17 able to travel that much. Smaller
18 companies that were in different parts of
19 the country.

20 So we would have regional
21 round tables where the smaller companies
22 would be able to get to a central
23 location and we'd come in and update them
24 on key issues.

1 Q. Okay. So this is an example
2 of updating some of these smaller
3 companies about the industry compliance
4 guidelines and the process that was
5 engaged to develop them and roll them
6 out?

7 A. That seems to be, yes, what
8 it was.

9 Q. It's got some summary of DEA
10 reaction on Page 213085 which is
11 consistent with the notes that Ms. Ducca
12 took of the first meeting. Agree?

13 MS. CHARLES: Object to
14 form.

15 THE WITNESS: Yes.

16 (Document marked for
17 identification as Exhibit
18 HDA-Kelly-26.)

19 BY MR. PIFKO:

20 Q. I'm handing you what's
21 marked as Exhibit 26. These are
22 Ms. Ducca's notes from the second meeting
23 with DEA on suspicious orders which was
24 attached to Exhibit 8, I believe.

1 For the record, it's
2 Bates-labeled CAH_MDL2804_02489191
3 through 196. Take a minute to review
4 this, and let me know when you're done.

5 A. Okay.

6 Q. Are you done? You reviewed
7 this?

8 A. I reviewed it, yes.

9 Q. So these are Ms. Ducca's
10 notes of the second meeting with DEA,
11 correct?

12 A. Yes.

13 Q. And if you recall, from the
14 notes from the first meeting, one of the
15 comments was that they welcomed DEA's
16 input on the draft that had been shared
17 at the prior meeting, agree?

18 A. Yes.

19 Q. And so then, this is DEA
20 providing its comments on the industry
21 compliance guidelines that had been
22 provided to them at the prior meeting,
23 agree?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: Yes.

3 BY MR. PIFKO:

4 Q. And it's got the attendees
5 here from DEA, it includes Linden Barber,
6 Cathy Gallagher, Robert Gleason, agree?

7 A. Yes.

8 Q. And then from HDMA, we've
9 got Ms. Ducca, Scott Melville. And
10 you've got outside counsel, Robert
11 Burnett, Richard Cooper, and David
12 Durkin, agree?

13 A. Yes.

14 Q. Okay. So they just go
15 through the draft guidelines that were
16 provided to them, which are the ones that
17 were in Exhibit 21.

18 So then, it goes through
19 page by page providing thoughts and
20 comments DEA has, agree?

21 A. Yes, that's what these notes
22 do.

23 Q. That's what's reflected in
24 Exhibit 26, correct?

1 A. Yes.

2 Q. Okay. So one comment DEA
3 has is that, "It's recommended that you
4 add into the outline that once an order
5 is determined to be suspicious, it
6 shouldn't be shipped. DEA understood
7 that it was in the body of the
8 guidelines, but they wanted to see it
9 upfront in the outline as well." Agreed?

10 MR. WEINSTEIN: Objection to
11 form.

12 THE WITNESS: I'm sorry,
13 where -- where --

14 BY MR. PIFKO:

15 Q. Page 3.

16 A. Page 3, I'm sorry.

17 Q. No I'm on the first page of
18 Exhibit 26. But I'm looking at the
19 comment from Page 3.

20 A. Oh, I'm sorry. Okay, yes.

21 Q. DEA is just emphasizing that
22 the -- if an order is suspicious, it
23 shouldn't be shipped. They want that up
24 in the front in the outline, even though

1 it's in the body of the document, agreed?

2 A. That's what this notes says,
3 yes.

4 Q. The comment for Page 4, Item
5 1B is saying that for a questionnaire
6 that might be to a distributor's
7 customer, DEA wants the industry to be
8 aware that even if you obtain a signed
9 document, that's not going to be a
10 defense; distributors have to do more to
11 identify the legitimacy, agree?

12 MR. WEINSTEIN: Objection to
13 form.

14 THE WITNESS: Yes, that's
15 what it says.

16 BY MR. PIFKO:

17 Q. Turning to the second page.
18 It says, a comment halfway down the page
19 on Page -- the comment for Page 6.
20 There's actually two. I'm looking at
21 the -- oh, there's actually three. I'm
22 looking at the second one. It says,
23 "Several times they" -- which is DEA,
24 "they said that the procedures" --

1 "procedures used by members should be
2 robust and adaptable," agree?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: That's what it
6 says.

7 BY MR. PIFKO:

8 Q. Okay. And then the longer
9 comment here for Section 2, monitoring on
10 suspicious orders, the second paragraph
11 here, it says, "DEA seemed to think that
12 thresholds focus primarily on volumes and
13 they expressed the view that an exclusive
14 or even principal focus on volumes is
15 inadequate."

16 Do you see that?

17 A. I do.

18 Q. Do you agree that that's
19 what DEA told HDMA during this meeting?

20 A. I have no reason to doubt
21 what's written here.

22 Q. Okay. And that's what's
23 written here, correct?

24 A. That's what's written here.

1 Q. "They also want the initial
2 screen of orders to focus on A, patterns
3 of ordering, comparing the present order
4 to, one, past orders from the same
5 customer including whether the frequency
6 of orders is suspicious; two, orders from
7 similar customers; and, three, orders
8 from other establishments of the same
9 type in the locale or region." Agree?

10 A. That's what it says.

11 Q. Okay. And then they also
12 want the initial screens of orders to
13 focus on combination of controlled
14 substances ordered, agree?

15 A. That's what it says, yes.

16 Q. Then going to the third
17 page, at the top, another comment that
18 DEA made here, it says, was that the term
19 "order of interest" did not have legal
20 standing.

21 Do you see that?

22 A. I do.

23 Q. Okay. And that was
24 something that DEA conveyed at this

1 meeting, correct?

2 A. Again, I'll take it from
3 this, yes, that they did that.

4 Q. And then it says, "DEA
5 emphasized that orders should not remain
6 in the orders of interest category for
7 lengthy periods."

8 Do you see that?

9 A. Yes.

10 Q. "They should be investigated
11 expeditiously and promptly resolved as
12 either suspicious or not suspicious."
13 Agree?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: That's what it
17 says, yes.

18 BY MR. PIFKO:

19 Q. Okay. Then there's some
20 comments about the language about
21 thresholds that was in the draft industry
22 compliance guidelines.

23 Do you see that section?

24 A. I do.

1 Q. Okay. So the first is that,
2 "DEA thought it might be interpreted to
3 mean excessive volumes only. And then
4 HDMA responded that their intent was to
5 be broader and to include frequency as a
6 factor."

7 Do you see that?

8 A. I do.

9 Q. Okay. "DEA asked HDA to
10 expand the explanation of thresholds,"
11 agreed?

12 A. That's what it says, yes.

13 Q. And then, "DEA asked that
14 the industry compliance guidelines say
15 the drug or drugs that cause an order to
16 be an order of interest should not be
17 shipped where the order is an order of
18 interest."

19 Do you see that?

20 A. I do.

21 Q. Okay. You agree that that
22 was something that the DEA conveyed at
23 this meeting?

24 A. Again, I have no reason to

1 doubt what was stated here on this paper.

2 Q. And then finally, it says,
3 "DEA suggested that we delete the second
4 paragraph under C, develop thresholds to
5 identify orders of interest."

6 Do you see that?

7 A. I do.

8 Q. It says, "DEA has backed
9 away from the standard of three times the
10 monthly overage order for Schedule II and
11 ARCOS-reportable Schedule III products.
12 DEA suggested that we substitute a
13 paragraph based on more recent DEA
14 guidance."

15 Do you see that?

16 A. I do.

17 Q. So you understood that DEA
18 was communicating here not to use the
19 three times multiplier, correct?

20 MR. WEINSTEIN: Objection to
21 form. Foundation.

22 THE WITNESS: That seems to
23 be what this indicates, yes.

24 BY MR. PIFKO:

1 Q. Going to Page 4. There is
2 some discussion about how to evaluate
3 orders that aren't just of high volume.
4 It says, "They gave the example of an
5 internet pharmacy that might be ordering
6 from multiple distributors and that might
7 not order enough to go over a threshold
8 over a period of time, but could be
9 identified by a pattern of how and when
10 they ordered.

11 "For example, they thought
12 if a pharmacy ordered only every three to
13 four months, but then when they did so,
14 ordered a large volume, that might be a
15 signal the pharmacy was doing business
16 with several distributors and rotating
17 which one they ordered from?"

18 Do you see that?

19 A. I do.

20 Q. That was something that was
21 communicated?

22 A. It's written here. I have
23 no reason to doubt that that was what was
24 stated.

1 Q. Okay. And then we go to the
2 section on Page 8 in the guidelines,
3 "Stop shipments of an order of interest."

4 Do you see that?

5 A. I do.

6 Q. And then it says, "DEA asked
7 us to reemphasize that an order should
8 not be shipped" -- and it's underlined --
9 "if there was reason to believe there was
10 a problem."

11 Do you see that?

12 A. I do.

13 Q. So DEA made that point
14 again, correct?

15 A. Yes.

16 MR. WEINSTEIN: Objection to
17 form.

18 BY MR. PIFKO:

19 Q. And then it says, "In fact,
20 they asked us to add in that if one
21 controlled substance in the order could
22 be a problem, then other controlled
23 substances in the order may also be a
24 problem and the distributor should

1 consider holding the others."

2 Do you see that?

3 A. I do.

4 Q. Did I read that correctly?

5 A. You did.

6 Q. It's your understanding that
7 DEA communicated this to HDA in providing
8 comments on the guidelines, correct?

9 A. I have no reason to doubt
10 what's written here.

11 Q. They gave an example of an
12 order where the volume of hydrocodone
13 triggered a threshold, but that both
14 hydrocodone and alprazolam were included
15 in the same order.

16 Do you see that?

17 A. I do.

18 Q. And then it says, at the
19 bottom of that paragraph, "If one part
20 was suspicious, wouldn't all of it be
21 suspicious?"

22 Do you see that?

23 A. I do.

24 Q. Do you agree that that was

1 something communicated at this meeting?

2 MS. CHARLES: Object to
3 form.

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: Again, that's
7 written clearly here that that's
8 what they said.

9 BY MR. PIFKO:

10 Q. Then at the last page --
11 part in that section it says, "DEA's
12 point was that in some circumstances, the
13 connection between that drug and another
14 drug in the order should lead the
15 wholesaler not to ship the other drug as
16 well. Again, in their view, looking at
17 volume ordered drug by drug is not
18 enough, and basing thresholds solely on
19 volume is not enough. Even if an order
20 for a drug that does not meet a volume
21 threshold may be suspicious in light of
22 other aspects of the order."

23 Do you see that?

24 MR. WEINSTEIN: You didn't

1 read the full paragraph.

2 BY MR. PIFKO:

3 Q. Do you see where I was
4 reading?

5 A. I did -- I did see where you
6 were reading, yes.

7 Q. Okay. You understood that
8 DEA communicated that during this
9 meeting?

10 A. Again, I have no reason to
11 doubt what's written here.

12 Q. I want to go to the last
13 page of this document. The comment from
14 Page 11, "DEA asked us to emphasize that
15 suspicious order must be reported to DEA
16 whether the wholesaler ships or not, and
17 to emphasize that timeliness of notice is
18 very important."

19 Do you see that?

20 A. I do.

21 Q. Do you agree that that was
22 something communicated during this
23 meeting?

24 A. I do.

1 Q. Then there's some -- a
2 section, "Additional Recommendations."

3 "DEA asked us to further" --
4 "to either expand this bullet or create a
5 new bullet to highlight the distributor's
6 own experience may indicate a need to
7 revise their system for suspicious order
8 monitoring."

9 Do you see that?

10 A. I do.

11 Q. So you understood that DEA
12 was saying, based on a distributor's own
13 experience, they might need to make
14 changes or improvements to their system
15 over time?

16 MR. WEINSTEIN: Objection to
17 form.

18 BY MR. PIFKO:

19 Q. Correct?

20 MR. WEINSTEIN: Same
21 objection.

22 THE WITNESS: That seems to
23 indicate what -- yes, what was
24 said.

1 BY MR. PIFKO:

2 Q. And then there's additional
3 comments that DEA raised that are
4 provided in bullet points here at the
5 end. Agree?

6 A. I see them.

7 Q. Five of them?

8 A. Yes.

9 Q. One is yet another comment
10 that if an order is -- there's concerns
11 or questions, it shouldn't be shipped,
12 agree?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: The first
16 bullet point?

17 BY MR. PIFKO:

18 Q. Yeah. That's what it says?

19 A. That's what it says.

20 Q. They want reports on all
21 orders, even if it's not shipped?

22 A. On all suspicious orders.

23 Yes. Bullet Point 2.

24 Q. Again, a comment about

1 timeliness in Bullet 3, agree?

2 A. Yes.

3 Q. And then 4, it says, "DEA
4 wants reports of suspicious orders even
5 if there is some question about the
6 dispenser status as a customer. For
7 example, if during a background check of
8 a potential customer, the customer
9 indicates that they might be placing
10 orders that could be suspicious, DEA
11 wants to know, even if the pharmacy in
12 question does not become a customer."

13 Agree, that's what it says?

14 A. That's what it says, yes.

15 Q. So you understood that DEA
16 communicated that as well during this
17 meeting?

18 A. Again, I have no reason to
19 doubt what's written here.

20 Q. Okay. We know these
21 comments were shared with Cardinal,
22 because we have the e-mail.

23 To your knowledge, in the
24 ordinary course of HDA's processes and

1 procedures, these would -- these would
2 have been shared with other members as
3 well, correct?

4 MR. WEINSTEIN: Objection to
5 form.

6 MS. WICHT: Objection to
7 form.

8 THE WITNESS: Again, I can't
9 say for certain. This is labeled
10 as a draft. I'm not sure if it
11 was sent to the RAC or another
12 group, until -- again, all I have
13 is the form in front of me so...

14 I would -- I would imagine
15 so, that usually we sent -- we're
16 usually in the habit of
17 summarizing those meetings and
18 sending them out to the regulatory
19 affairs committee.

20 BY MR. PIFKO:

21 Q. And as we looked at in one
22 of the other documents, the outcome of
23 these meetings was critical to forming
24 HDA's future strategies, correct?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: It was -- I
4 mean feedback from the DEA was an
5 important component to finalizing
6 and -- and fine-tuning the ICGs,
7 yes.

8 BY MR. PIFKO:

9 Q. And developing other
10 strategies. Remember we looked at that
11 discussion of strategy for the Hill. It
12 said that the meetings under industry
13 compliance guidelines were going to be
14 key to formulating additional strategies,
15 agreed?

16 A. Yes.

17 Q. Okay. So HDA certainly
18 would have shared the views of DEA to its
19 members after this meeting, agree?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: Again, I don't
23 doubt that they did. I just --
24 I'm looking at a draft document.

1 So again, I don't doubt that
2 this was finalized and the edits
3 made here were incorporated and a
4 final document was submitted to
5 the regulatory affairs committee.

6 BY MR. PIFKO:

7 Q. And you agree that the
8 members of the regulatory affairs
9 committee would have been interested to
10 know how this DEA meeting turned out,
11 correct?

12 MR. WEINSTEIN: Objection to
13 form.

14 MS. CHARLES: Objection.
15 Form.

16 MS. MACKAY: Objection.

17 MS. ROLLINS: Foundation.

18 MS. WICHT: Objection to
19 form.

20 MR. WEINSTEIN: Foundation.

21 THE WITNESS: I think -- I
22 think they would be interested,
23 yes.

24 BY MR. PIFKO:

1 Q. I'm handing you what's
2 marked as Exhibit 27.

3 (Document marked for
4 identification as Exhibit
5 HDA-Kelly-27.)

6 BY MR. PIFKO:

7 Q. You don't need to read this
8 thing in its entirety. But this is the
9 final guidelines, correct? You can take
10 a minute to review it. That's all I want
11 to ask you.

12 For the record, Exhibit 27
13 is a document Bates-labeled
14 HDA_MDL_00218651 through 218665.

15 A. Yes, I would agree that this
16 is the final version of the industry
17 compliance guidelines.

18 (Document marked for
19 identification as Exhibit
20 HDA-Kelly-28.)

21 BY MR. PIFKO:

22 Q. I'm handing you what's
23 marked Exhibit 28, single-page document,
24 a letter from the DEA dated October 17,

1 2008, Bates-labeled CAH_MDL2804_02489203.
2 Take a minute to review this. This is a
3 letter HDA received after finalizing the
4 guidelines from DEA, correct?

5 A. I'm sorry. Could you
6 restate it?

7 Q. Take a minute to review it.
8 And let me know when you're done.

9 A. All right.

10 Q. Okay. This is a letter that
11 DEA receive -- or sorry, DEA sent to HDA
12 after the guidelines were completed,
13 correct?

14 A. That's my understanding,
15 yes.

16 Q. This is to HDA's president,
17 John Gray?

18 A. Yes.

19 Q. Okay. It says in the first
20 paragraph, second sentence, "The elements
21 set forth in the industry compliance
22 guidelines reporting suspicious orders
23 and preventing diversion of controlled
24 substances are important to sustaining

1 effective controls to guard against
2 diversion of controlled substances."

3 You agree that's what it
4 says?

5 A. That's what it says, yes.

6 Q. Second paragraph, last
7 sentence, "All distributors must
8 implement processes and procedures to
9 effectively ensure that controlled
10 substances are not diverted to illicit
11 use."

12 Do you agree with me that's
13 what it says?

14 A. Yes.

15 Q. Third paragraph, first
16 sentence, "Although diversion control is
17 not a one-size-fits-all effort, companies
18 that implement processes and procedures
19 that effectively accomplish these
20 objectives will do much to ensure that
21 vital controlled substances are not
22 diverted to illegitimate uses."

23 Agree that's what it says?

24 A. Yes.

1 Q. When HDA received this, did
2 it send this letter to its members?

3 MS. MACKAY: Objection to
4 form.

5 THE WITNESS: I imagine it
6 did. This is the type of
7 correspondence that we would make
8 available to the members.

9 MR. PIFKO: We'll take a
10 break after this document.

11 (Document marked for
12 identification as Exhibit
13 HDA-Kelly-29.)

14 BY MR. PIFKO:

15 Q. Handing you what's been
16 marked as Exhibit 29. For the record,
17 Exhibit 29 is a webinar slide
18 presentation dated Friday, November 14th,
19 2008. The title "Industry Compliance
20 Guidelines. Reporting Suspicious Orders
21 and Preventing Diversion of Controlled
22 Substances." It's Bates-labeled
23 HDA_MDL_000145918 through 145968.

24 Take a minute to review it.

1 I only have a couple of questions about a
2 couple of the slides.

3 A. Okay.

4 Q. So you recall in the first
5 meeting with DEA about the industry
6 compliance guidelines on April 15, 2008,
7 one of the thing HDA told DEA that it was
8 going to engage in an educational
9 outreach concerning the guidelines,
10 correct?

11 A. Correct.

12 Q. Okay. Do you understand
13 that to be a part of the educational
14 outreach?

15 A. I do, yes.

16 Q. Do you know who this was
17 given to?

18 A. I do not know. I have no
19 idea who the participants were.

20 Q. This is a webinar. Is it
21 common practice for HDA to provide
22 webinars?

23 A. Yes.

24 Q. And it provides webinars to

1 its members?

2 MR. CRAWFORD: Objection to
3 form.

4 THE WITNESS: Its -- yeah,
5 its core members. Its distributor
6 members --

7 BY MR. PIFKO:

8 Q. Okay.

9 A. -- on technical issues.

10 Q. So it's HDA's practice to
11 provide webinars to core distributor
12 members, correct?

13 A. Yes.

14 Q. And this is a webinar dated
15 Friday, February (sic) 14, 2008, agreed?

16 A. Yes.

17 Q. About a month after you got
18 the letter from DEA, Exhibit 28, agree?

19 A. Yes.

20 Q. It's got two presentations,
21 one from Ms. Ducca, and one from David
22 Durkin, agree?

23 A. Yes.

24 Q. So it's got some background

1 about how the guidelines were developed
2 and why they were developed. If you look
3 at Slide 8, there's a section,
4 history/background.

5 A. Yes.

6 Q. Okay. One of the points of
7 history and background that's provided on
8 Slide 8 is that intensity stepped up, and
9 the DEA sent those three Rannazzisi "Dear
10 Registrant" letters and suspended
11 distributors' registration, agree?

12 A. Yes.

13 Q. And that was part of what
14 led to the development of these industry
15 compliance guidelines, correct?

16 A. Yes.

17 Q. Then there is -- then next
18 slide, Slide 9 is, what is driving the
19 DEA. So why -- why is that happening,
20 agree? Why are we getting these "Dear
21 Registrant" letters and suspension of
22 registrations?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: These are,
2 yeah, several criteria that were
3 listed, yes.

4 BY MR. PIFKO:

5 Q. Okay. It says prescription
6 drug abuse. And it talks about increase
7 in prescribing for pain, nonmedical
8 prescription drug use is up 80 percent
9 from 2000. Am I reading that correct?

10 A. That's what -- yes.

11 Q. And there is some discussion
12 about the "Dear Registrant" Rannazzisi
13 letters. Some of this we've seen in the
14 other presentations, agree? Such as the
15 October 31, 2008, one? Or I'm sorry,
16 January 31, 2008, one?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: Yes.

20 BY MR. PIFKO:

21 Q. Then you go to Slide 15. It
22 tells you the purpose of the industry
23 compliance guidelines and the DEA
24 communications, agree?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: Yes.

4 BY MR. PIFKO:

5 Q. So, the purpose -- one of
6 the purposes is to head off further
7 enforcement of regulatory action, agree?

8 A. That's what it states.

9 Q. One of them is to
10 demonstrate our members' commitment.

11 Do you see that?

12 A. Yes.

13 Q. Another one says to see
14 distributors as part of the solution.

15 Do you see that?

16 A. Yes.

17 Q. If you go to Slide 24. Some
18 additional advice on what's a suspicious
19 order from DEA, agreed?

20 A. It says, "Anecdotal advice
21 from DEA," yes.

22 Q. And it's got seven bullet
23 points about criteria that can make an
24 order suspicious, agree?

1 A. Yes there are certain bullet
2 points, yes.

3 Q. If you go to Page 29, it's
4 got a timeline and set of events of
5 background about the industry compliance
6 guidelines development.

7 Do you see that?

8 A. I'm sorry.

9 Q. 29?

10 A. Yes.

11 Q. Are you there?

12 A. I'm on Slide 29, yes.

13 Q. So it says, "The regulatory
14 affairs committee" -- that's the
15 committee that developed them, correct?

16 A. Yes.

17 Q. And then they were reviewed
18 by counsel, yes?

19 A. That's correct.

20 Q. And then outreach to related
21 interest groups. That includes the Pain
22 Care Forum, correct?

23 A. And pharmacy groups, yes,
24 among others, yes.

1 Q. Then the executive committee
2 approved them, correct?

3 A. That's correct.

4 Q. And then there's these DEA
5 meetings that we just discussed, right?

6 A. Correct.

7 Q. April 15th, June 4th, and
8 Ms. Ducca said she didn't make minutes of
9 the September 5th one, agreed?

10 A. Yes.

11 Q. And then you get the letter
12 on October 23rd that we looked at
13 Exhibit 28?

14 A. Yes.

15 MR. PIFKO: We can take a
16 break.

17 THE VIDEOGRAPHER: The time
18 is 2:12 p.m. We are going off the
19 record.

20 (Short break.)

21 THE VIDEOGRAPHER: The time
22 is 2:29 p.m. We are back on the
23 record.

24 (Document marked for

1 identification as Exhibit

2 HDA-Kelly-30.)

3 BY MR. PIFKO:

4 Q. I'm handing you what's
5 marked Exhibit 30. It's an e-mail,
6 two-page e-mail with an attachment,
7 one-page attachment, Bates-labeled
8 HDA_MDL_000080421 through 423.

9 Take a minute to review it
10 and let me know when you're done.

11 Are you ready?

12 A. Yes.

13 Q. Are you familiar with this
14 discussion; you were at HDA at this time,
15 correct?

16 A. I was at HDA at this time,
17 yes. I am not familiar with this
18 particular e-mail, but I understand the
19 correspondence between the communications
20 department and -- and Anita Ducca.

21 Q. Okay. So Farah Qureshi, am
22 I -- am I saying that right?

23 A. Yes.

24 Q. She's a communications

1 manager?

2 A. Yes.

3 Q. So she is responsible for
4 providing initial drafts of public --
5 public statements that HDA might post?

6 A. It's --

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: Primarily just
10 with what goes up onto the
11 internet and what gets -- public
12 facing. And all the policy
13 documents are developed usually
14 inside the government affairs
15 department.

16 BY MR. PIFKO:

17 Q. Okay. So Farrah's job is to
18 draft materials that will be on HDA's
19 website?

20 A. Yes. And kind of, you know,
21 position them and pretty them up for the
22 website.

23 Q. Okay. So she prepares this
24 one-pager on prescription drug abuse and

1 diversion that is attached as the last
2 page of Exhibit 30. Agree?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Yes.

6 BY MR. PIFKO:

7 Q. And then Anita Ducca
8 provides some comments in this e-mail
9 dated Wednesday June 12, 2013. Agree?

10 A. Yes.

11 Q. And then she actually
12 attaches the redline that's -- and the
13 redline is what is the second page,
14 agree?

15 A. Yes, it appears so.

16 Q. Okay. So one of Anita's
17 comments is, she says, "Although there
18 are some examples of what our members do,
19 I'm hesitant to include anything like
20 that."

21 You see that in the third
22 paragraph?

23 A. Yes.

24 Q. And then she says, "Not all

1 our members are doing what HD Smith
2 does."

3 Do you see that?

4 A. Yes.

5 Q. "If DEA sees this, which
6 they are likely to at some point, they
7 may question why all our members aren't
8 doing it."

9 Do you see that?

10 A. Yes.

11 Q. "Sort of like how they took
12 our ICG and included it in their legal
13 filing against Walgreens Distribution
14 Center, claiming that there was an
15 industry standard that Walgreens should
16 have known about and been following."

17 Do you see that?

18 A. I do.

19 Q. There were some frustration
20 at HDA that DEA had cited the industry
21 compliance guidelines as an industry
22 standard and used them against Walgreens?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: I don't know
2 that there was frustration. I
3 think we were -- we were slightly
4 concerned that a document that was
5 voluntary guidelines was cited in
6 a -- in a proceeding by DEA
7 against a non-HD member or non --
8 at that point still HDMA or HDA at
9 that point. So that was the
10 concern.

11 BY MR. PIFKO:

12 Q. I'm handing you what's
13 marked as Exhibit 31.

14 (Document marked for
15 identification as Exhibit
16 HDA-Kelly-31.)

17 BY MR. PIFKO:

18 Q. This is a chronology of
19 HDMA/HDA executive committee and board of
20 directors' drug abuse and diversion
21 discussions at meetings and conference
22 calls. It's dated January 2, 2018.

23 It's kind of lengthy. I
24 just want to point you to a particular

1 passage that's relevant to the suspicion
2 about the industry compliance guidelines
3 on Page 7.

4 And for the record,
5 Exhibit 31 is Bates-labeled
6 HDA_MDL_000155930 through 155946.

7 MR. WEINSTEIN: 47 actually.

8 MR. PIFKO: 47. Sorry.

9 Thanks.

10 BY MR. PIFKO:

11 Q. And these notes were
12 prepared by Ms. Ducca. I want to turn
13 your attention to Page 7.

14 MR. WEINSTEIN: Was that a
15 question or was that a statement?

16 MR. PIFKO: No, I'm stating
17 to you.

18 THE WITNESS: I don't know
19 that these were prepared. This is
20 a summary of -- of board minutes,
21 I believe. So it was -- I don't
22 think this was prepared by Anita
23 Ducca.

24 BY MR. PIFKO:

1 Q. Do you have any reason to
2 dispute that the statements in here are
3 accurate with respect to discussions at
4 the board meetings?

5 A. No, I have no reason to
6 dispute that.

7 Q. Okay. I want to direct you
8 to Page 7 which is HDA_MDL_00015936. Are
9 you there?

10 A. Yes.

11 Q. Second full paragraph, or
12 look at -- second paragraph here.

13 A. Yep.

14 Q. Second sentence it says,
15 "DEA has been referring to the industry
16 compliance guidelines on suspicious
17 orders and certain legal documents
18 resulting in the implication that it is
19 an industry standard. Since these
20 guidelines were never intended to
21 constitute a standard, they have been
22 taken down from the HDMA website at the
23 direction of the government public policy
24 council."

1 Did I read that correctly?

2 A. Yes, you did.

3 Q. Is that consistent with your
4 understanding of --

5 A. Yes, it is.

6 Q. -- why the guidelines were
7 taken down?

8 A. Yes, it is.

9 (Document marked for
10 identification as Exhibit
11 HDA-Kelly-32.)

12 BY MR. PIFKO:

13 Q. Handing you what's marked as
14 Exhibit 32. It's a two-page document
15 Bates-labeled HDA_MDL_00081415 and 416.

16 Take a minute to review this
17 and let me know when you're done.

18 A. Okay.

19 Q. I just wanted to direct your
20 attention to second paragraph on the
21 first page.

22 "The regulatory affairs
23 committee and federal government affairs
24 committee told its members that there was

1 some consideration about updating the
2 guidelines, but ultimately it was decided
3 that they would be replaced with a
4 statement to the effect that the industry
5 is very committed to compliance."

6 And there was a draft that
7 was exchanged with members, agree?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: Yes, that's
11 what this says.

12 BY MR. PIFKO:

13 Q. And that's what happened?

14 A. I don't recall exactly what
15 the process was between the ICGs coming
16 down and a statement going up in its
17 stead. But again, I have no reason to
18 doubt that this process described here is
19 accurate.

20 Q. Handing you what's marked as
21 Exhibit 33.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-33.)

1 BY MR. PIFKO:

2 Q. For the record Exhibit 33 is
3 a Word document that was -- file name --
4 name GAO Meeting on DEA Draft, TPs,
5 092010. It's Bates-labeled HDMA -- or
6 sorry, HDA_MDL_000139905 to 000139910.
7 Take a minute to review it and let me
8 know when you're done.

9 A. Okay.

10 Q. You done?

11 A. Yes.

12 Q. So if you recall, we were
13 looking earlier at a document, that
14 document about the strategy for testimony
15 on the Hill. Do you recall that?

16 A. Yes, I do.

17 Q. And one of the tactics that
18 was discussed there was getting a
19 congressperson to talk to the DEA to
20 address the industry's concerns. Do you
21 recall that?

22 A. I do.

23 Q. Another tactic that HDA was
24 considering was communicating with the

1 Government Accountability Office about
2 the -- its concerns about the DEA,
3 correct?

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: I don't know
7 if that was part of that. I
8 didn't -- was that part of that?

9 BY MR. PIFKO:

10 Q. Irrespective of that
11 document, I'm just asking you --

12 A. It is --

13 Q. -- if that was another
14 tactic that HDA was investigating?

15 MR. WEINSTEIN: Objection to
16 form.

17 THE WITNESS: Again, we
18 don't have the ability to launch
19 GAO investigations, but we can
20 talk to members of Congress who
21 may think that's a correct course
22 of action.

23 BY MR. PIFKO:

24 Q. Okay. And so that was

1 something that HDA was exploring about
2 whether there could be a dialogue with
3 GAO about the industry's concerns about
4 the DEA, correct?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: Again I don't
8 know if we -- if we specifically
9 requested that. I know that this
10 GAO report was requested by
11 members of Congress.

12 BY MR. PIFKO:

13 Q. Okay. These are talking
14 points about the industry's concerns that
15 would be presented at the GAO, correct?

16 A. Correct.

17 Q. So, this talks about, I'm on
18 the second page of the document. It
19 first says, "Background on HDMA, who we
20 represent, show the graphic of wholesale
21 distribution we have online, number of
22 members, et cetera."

23 So in connection with the
24 discussion, there would have been a

1 discussion about who the members are that
2 are represented by HDA, correct?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Yes.

6 BY MR. PIFKO:

7 Q. And then this identifies
8 recent concerns. Do you see that
9 discussion in Section 4 here?

10 A. Yes, I see Section 4.

11 Q. It says, "Recently DEA has
12 exerted extreme pressure on wholesale
13 distributors to take controlled
14 substances suspicious order
15 responsibilities much further."

16 Do you see that?

17 A. I do.

18 Q. Do you agree that was a
19 concern from HDA and its distributor
20 members?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: It was.

24 BY MR. PIFKO:

1 Q. And then it gives bullet
2 points elaborating on that concern,
3 agree?

4 A. It appears to, yes.

5 Q. And the first one is, "DEA
6 invited members of the distribution
7 industry, firm by firm to a meeting where
8 DEA point blank told them that they
9 should identify customers who are selling
10 for illicit purposes, e.g., pill mills, or
11 illicit internet pharmacies such as those
12 filling orders without a prescription."

13 Do you see that?

14 A. I do.

15 Q. So that was part of the
16 basis for the HDA and its members'
17 concerns about DEA's pressures to take
18 controlled substances order
19 responsibilities further?

20 MS. WICHT: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, that

1 was -- that was an event or a
2 process that DEA had undertaken.
3 I have no reason to doubt that
4 that was part of the pattern of
5 concern.

6 BY MR. PIFKO:

7 Q. And then another part of
8 that concern was that that action was
9 followed by revoking several
10 registrations in 2007, agreed?

11 A. That's what is stated, yes.

12 Q. And then it says, "HDA went
13 to great lengths to seek resolution with
14 DEA." And then it's got some bullet
15 points. Some of them are discussing the
16 industry compliance guidelines we just
17 discussed, agree?

18 A. Yes.

19 Q. And then in all bold, all
20 caps, it says, "Despite these efforts,
21 DEA has revoked another wholesale
22 distributor registration spring 2010."

23 Do you see that?

24 A. I do.

1 Q. So the DEA's revoking or
2 suspending registrations, was a
3 significant concern for HDA and its
4 members?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: Yes.

8 BY MR. PIFKO:

9 Q. If you go to the page --
10 they are not numbered here --
11 HDA_MDL_000139907. There's a heading,
12 "Key Concerns."

13 A. I see it.

14 Q. So this summarizes key
15 concerns that HDA and its members had
16 with respect to the DEA's enforcement
17 activities, correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 THE WITNESS: Yes, at the
21 time.

22 BY MR. PIFKO:

23 Q. So one of them is, it says,
24 "It's unreasonable for DEA to expect a

1 distributor to seek information about
2 pharmacies that they are barred from,
3 either through confidential business
4 practices or legal restrictions, e.g.,
5 HIPAA."

6 Do you see that?

7 A. Yes, I do.

8 Q. That was a key concern?

9 MS. CHARLES: Objection to
10 form.

11 THE WITNESS: Again, this
12 means that they were unreasonable
13 for DEA to expect distributors to
14 get prescribing information that
15 would have been HIPAA protected.

16 BY MR. PIFKO:

17 Q. And then it says under here,
18 "DEA has asked distributors where
19 pharmacies' prescriptions came from, also
20 to research the pharmacies' customer
21 base.

22 So was that -- that was the
23 basis for that concern?

24 A. I think that's part of the

1 concern, yes.

2 Q. Then it says, "Even if the
3 distributor does their due diligence
4 regarding a customer, there's no
5 guarantee that the pharmacy will tell the
6 truth."

7 That was another concern?

8 A. That is -- that is a
9 concern, yes.

10 Q. Then here it says, again,
11 "DEA used an extreme tactic by suspending
12 a license. This action is intended for
13 when there is an imminent threat to the
14 public health and safety."

15 Do you see that?

16 A. Yes.

17 Q. So again, this tactic of
18 suspending or revoking registrations was
19 a critical concern for HDMA and its
20 members, correct?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: Yes.

24 BY MR. PIFKO:

1 Q. I want to direct your
2 attention back to Exhibit 31, on the
3 first page of it. Are you there?

4 A. I am.

5 Q. There's a note about a
6 conference call with the executive
7 committee on April 6, 2012.

8 Do you see that?

9 A. Yes.

10 Q. It says, "President John
11 Gray thanked the executive" -- "thanked
12 the executive committee members for
13 agreeing to participate in a conference
14 call to address recent activity with
15 respect to suspicious order monitoring
16 and the role of healthcare distributors."

17 Do you see that?

18 A. I do.

19 Q. And then it says, "HDMA has
20 testified before Congress and prepared an
21 amicus brief for filing with the federal
22 court of appeals in the Cardinal v.
23 Holder litigation."

24 Do you see that?

1 A. I do.

2 Q. HDA's members authorized HDA
3 to file that amicus brief in the federal
4 court of appeals, correct?

5 A. They did.

6 Q. Okay. And then it says
7 here, "Chairman Moody and Vice Chairman
8 Neu expressed concern about the trend of
9 recent developments and thought it time
10 for executive committee to review recent
11 events and plot a course going forward."

12 Do you see that?

13 A. I do.

14 Q. Okay. You understand
15 Chairman Moody is from Cardinal?

16 A. No. Chairman Moody at the
17 time was Dave Moody from North Carolina
18 Mutual.

19 Q. Okay. That is another
20 distributor member?

21 A. That is.

22 Q. Okay. And Chairman Neu was
23 from AmerisourceBergen?

24 A. Vice Chairman Neu at the

1 time was from AmerisourceBergen, yes.

2 Q. Vice chairman.

3 (Document marked for
4 identification as Exhibit
5 HDA-Kelly-34.)

6 BY MR. PIFKO:

7 Q. Handing you what's marked as
8 Exhibit 34. Take a minute to review that
9 and let me know when you're done.

10 A. Okay.

11 Q. To put some time frame
12 context in this, are you aware that on
13 February 6, 2012, the DEA had announced
14 that it suspended the license of Cardinal
15 Health's Lakeland distribution center?

16 MR. WEINSTEIN: Objection to
17 form.

18 THE WITNESS: That sounds
19 familiar.

20 BY MR. PIFKO:

21 Q. Okay. And so I just read
22 you from Exhibit 31 about the conference
23 call that's a few months later, two
24 months after that happened. Do you

1 recall we just discussed that?

2 A. Yes.

3 Q. And so Exhibit 34 says,
4 "After our last conference call on
5 April 6th" -- referring to that
6 conference call, agreed?

7 A. Yes. April 20th, yeah.

8 Q. Okay. And for the record
9 Exhibit 34 is an e-mail from John Gray
10 dated Friday, April 20, 2012, to Ken
11 Couch, Dale Smith, David Neu, Paul
12 Julian, Mike Kaufmann, David Moody and
13 Ted Scherr, copying Richard Frank from
14 HDA's outside counsel.

15 Agree?

16 A. Yes.

17 Q. Sorry, I can't remember if I
18 read the Bates number for this one.
19 00 -- HDA_MDL_00215234 to 236.

20 So at this executive
21 committee conference call, there was
22 concerns raised by the members again
23 about DEA's enforcement activity. Agree?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: Yes.

3 BY MR. PIFKO:

4 Q. And so then, there was a
5 decision that they needed to plot a
6 course going forward as it says in
7 Exhibit 31, agree?

8 A. Yes, that's what it says.

9 Q. Okay. So after that call,
10 John Gray says here that he met with
11 legal counsel Bob Barnett and Richard
12 Cooper from Williams & Connolly in
13 Washington DC, agreed?

14 A. Yes.

15 Q. And he comments -- I'm
16 reading from Exhibit 34 -- "Both
17 attorneys were very helpful several years
18 ago in initializing our original meetings
19 with DEA after the first outbreak of
20 ISOs" -- those are suspension orders,
21 correct?

22 A. Correct.

23 Q. "Given their experience and
24 knowledge of the political and legal

1 aspects of dealing with DEA, we updated
2 them on the industry's recent concerns
3 with DEA's latest efforts to thwart drug
4 diversion and abuse. Attached is a brief
5 summary of our discussion and conclusions
6 with several possible courses of action
7 HDMA could take. The entire list of
8 ideas is not necessarily mutually
9 exclusive, but does represent a wide
10 range of political actions the
11 association and the industry may consider
12 in an effort to alter the present
13 direction DEA is taking with respect to
14 suspicious order monitoring."

15 Did I read that correctly?

16 A. You -- potential options,
17 actions, not political actions.

18 Q. Sorry.

19 A. That's okay.

20 Q. So these are the same Bob
21 Burnett and Richard Cooper that we saw
22 who were participating in the meetings
23 with DEA with respect to the industry
24 compliance guidelines, correct?

1 A. Correct.

2 Q. And then the attached, the
3 following three pages of Exhibit 34 is
4 this document that says, according to the
5 e-mail, it's, "DEA options memorandum,
6 J. Gray edits," do you see that on the
7 first page? On the header of the e-mail,
8 that's what the attached document is?

9 A. Yes, yes, yes, yes, yes.

10 Q. So then it's a memo from
11 Mr. Gray to the HDMA executive committee
12 dated April 20, 2012. Agree?

13 A. Yes.

14 Q. And who is on the executive
15 committee at this time?

16 A. At this time it is Ken Couch
17 from Smith Drug, Dale Smith from
18 HD Smith, Dave Neu from
19 AmerisourceBergen, Paul Julian from
20 McKesson, Mike Kaufmann from Cardinal,
21 David Moody from North Carolina Mutual
22 and Ted Scherr from Dakota Drug.

23 Q. And so then this -- the
24 first paragraph says, again, some of the

1 same stuff that's in the e-mail. And
2 then the second paragraph says,
3 "Mr. Barnett and Mr. Cooper felt that new
4 legislation to specifically address our
5 concerns with DEA was highly unlikely to
6 be successful due to limited momentum in
7 that direction."

8 Do you see that?

9 A. I do.

10 Q. You understood that one of
11 the things HDA and its members were
12 considering was new legislation to
13 address the concerns with DEA?

14 MR. WEINSTEIN: Objection to
15 form.

16 MR. CRAWFORD: Objection to
17 form.

18 THE WITNESS: We had -- we
19 had -- again, one of the concerns
20 we had with the provisions that
21 DEA was implementing is that there
22 was no due process.

23 And so we thought that
24 possibly requesting legislative

1 process could help at least get
2 some type of notice and comment
3 back and forth with the DEA and
4 maybe securing that. If we
5 weren't successful in having the
6 DEA do that through their notice
7 and comment process, to maybe
8 request that legislatively.

9 BY MR. PIFKO:

10 Q. And what specifically would
11 the legislation include?

12 MR. WEINSTEIN: Objection to
13 form, foundation, scope.

14 THE WITNESS: Well, again,
15 we did -- we didn't get into
16 specifics of -- of what that
17 legislation -- we never drafted
18 legislation at that point in time.

19 But we were looking at
20 basically their interaction with
21 the registrant community on
22 suspicious orders.

23 BY MR. PIFKO:

24 Q. Later down the road you

1 ultimately did participate in what became
2 the Marino/Blackburn bill, correct?

3 A. That's correct.

4 MS. WICHT: Object to the
5 form of the question.

6 BY MR. PIFKO:

7 Q. Was that an outcrop of this
8 discussion?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: Not this
12 specific discussion.

13 BY MR. PIFKO:

14 Q. Okay. But it -- it grew
15 from these same concerns about DEA's
16 enforcement action and suspension of
17 licenses, correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 MS. CHARLES: Objection.

21 BY MR. PIFKO:

22 Q. Or registrations, sorry?

23 MR. WEINSTEIN: Same
24 objection.

1 THE WITNESS: It was part of
2 that, yes.

3 BY MR. PIFKO:

4 Q. Okay. So another thing
5 Mr. Gray writes in this memo is that
6 "Paul Barnett and Rich Cooper from
7 Williams & Connolly felt that the
8 industry may be better off asserting DEA
9 actions by taking even stronger
10 compliance measures."

11 Do you see that?

12 A. Yes.

13 Q. Did I read that correctly?

14 A. You did.

15 Q. Were you part of these
16 discussions?

17 A. I was in this meeting at
18 Williams & Connolly, yes.

19 Q. Okay. And so one of the
20 recommendations they said is that HDA's
21 members could avert action by improving
22 their compliance systems?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: That's -- I
2 mean, it says that they felt they
3 were better off averting DEA
4 actions by taking even stronger
5 compliance measures. That's
6 what's written in the memo.

7 BY MR. PIFKO:

8 Q. And that's what was
9 discussed at the meeting? You said you
10 were there?

11 A. I was there, yes.

12 Q. And that's consistent with
13 what was discussed there?

14 A. Yes.

15 Q. Let's go to Page 2 of the
16 attachment, I guess 3 of the document.
17 One of the other potential -- it has
18 other potential actions discussed here.

19 Do you see that?

20 A. I do.

21 Q. "Update HDMA industry
22 compliance guidelines." That was
23 something else that was being discussed
24 at that time?

1 A. Yes.

2 Q. And we know ultimately from
3 Exhibits 30 and 31 that -- that
4 ultimately the ICGs were replaced with a
5 statement on diversion, rather than
6 updated?

7 A. Yes.

8 Q. Another potential action is
9 to re-file the HDMA amicus brief in
10 Cardinal Health v. DEA, do you see that?

11 A. I do. In the appellate
12 case.

13 Q. So are you familiar with the
14 procedure? Why was there a need to
15 re-file that brief?

16 MR. WEINSTEIN: Objection to
17 form. Foundation.

18 THE WITNESS: Again, I'm not
19 familiar -- I don't know what the
20 discussion was. That was a
21 discussion with outside counsel
22 about that, and with the board.
23 So I don't -- I don't know what
24 the rationale was for that.

1 BY MR. PIFKO:

2 Q. Are these notes consistent
3 with your understanding of the
4 discussions that happened at that meeting
5 since you were there?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: Yes.

9 BY MR. PIFKO:

10 Q. Okay. Another potential
11 action, again going to Page 2 of the
12 notes, is, "Seek guidance from a
13 well-respected public relations firm to
14 improve industry image."

15 This was something else that
16 was considered?

17 A. Yes.

18 Q. Did you ever move forward
19 with that option?

20 A. We did.

21 Q. And who did you retain?

22 A. Processwise, after this
23 meeting, we've been through -- we've been
24 engaged with several public relations

1 firm. But I think this one led to an
2 initial engagement with APCO.

3 Q. And they developed the
4 crisis playbook, right?

5 A. That -- yes, that was their
6 development, yes. I don't know if that's
7 the specific name of it. But it was --

8 Q. But you're familiar with
9 that document?

10 A. Yes, that they developed,
11 yes.

12 Q. Okay. Another option here
13 is, "Petition DEA to put their
14 expectations into a regulation."

15 Can you explain what that
16 was?

17 A. Again, that was -- that was
18 the -- basically the process of -- you
19 know, the letters constituted the only
20 directives that we were getting from DEA
21 at the time, the letter to the
22 registrants. There was no process for
23 notice and comment in the development of
24 those letters. They were just basically

1 delivered.

2 We thought that if we
3 basically petitioned for a regulation to
4 go through a notice and comment
5 development process where the DEA would
6 basically draft a regulation, they would
7 notice it for public comment, there would
8 be public comment. They would review the
9 public comments. They would then
10 consider the public comment and finalize
11 the regulation.

12 But you would at least have
13 a process by which you could provide
14 concerns, suggestions, et cetera to the
15 DEA for the development of that
16 regulation.

17 Q. Another thing is to develop
18 a legal journal article concerning the
19 ambiguity of DEA expectations and
20 diversion prevention tactics. That was
21 something else that you discussed?

22 A. We -- it did, yes.

23 Q. And it said, "A
24 congressional hearing may be more

1 effective in this regard but would
2 unlikely" -- "be unlikely to happen prior
3 to the 2012 elections."

4 A. That's what it says, yes.

5 Q. How would you use a
6 congressional hearing to achieve the same
7 things that a legal journal article would
8 achieve?

9 A. I'm not exactly sure why --
10 why that was typed up that way. But,
11 again, it was to basically get some of
12 these concerns addressed in an open forum
13 for kind of probative discussion about,
14 you know, concerns we had and maybe
15 suggestions about processes that would
16 kind of more enlist the support of the
17 registrant community in addressing
18 suspicious orders.

19 Q. Were you involved in
20 subsequent phone discussions or in person
21 discussions with HDA's executive
22 committee after this memo was sent out?

23 MR. WEINSTEIN: Objection to
24 form.

1 THE WITNESS: I don't recall
2 the specific process of what
3 happened after this. I know that
4 this was something that the
5 executive committee asked us to
6 do. We did. We followed up with
7 them. We probably reported on it
8 at the next executive committee
9 meeting.

10 BY MR. PIFKO:

11 Q. But do you recall having any
12 discussions with the executive committee
13 members about these options?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: No. Again,
17 not prior to the executive
18 committee meeting.

19 BY MR. PIFKO:

20 Q. Are you aware that -- of
21 whether any of the executive committee
22 members asked how they could improve
23 their compliance measures consistent with
24 the advice that Bob Barnett and Rich

1 Cooper from Williams & Connolly provided?

2 MR. WEINSTEIN: Objection to
3 form. Foundation. Scope.

4 THE WITNESS: I'm not aware
5 of any specifics, suggestions or
6 conversations.

7 BY MR. PIFKO:

8 Q. To your knowledge did any of
9 them ask if there would be any
10 suggestions on how their compliance
11 efforts could be improved?

12 MR. WEINSTEIN: Objection to
13 form. Foundation. Scope.

14 THE WITNESS: Again, I don't
15 know that anybody asked. We did
16 provide some suggestions that were
17 provided by Mr. Cooper and
18 Mr. Barnett. But again, I don't
19 recall. And the correspondence
20 would have been with Mr. Gray
21 directly anyhow.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-35.)

1 BY MR. PIFKO:

2 Q. I'm handing you what's
3 marked as Exhibit 35. It's an e-mail
4 from you dated December 19, 2013,
5 Bates-labeled CAH_MDL2804_01110712
6 through 715.

7 Take a moment to review this
8 and let me know when you're done.

9 A. Okay.

10 Q. At some point a drug
11 diversion DEA strategy task force was
12 formed, correct?

13 A. Yes.

14 Q. Are you familiar with the
15 formation of that task force?

16 A. I am.

17 Q. Were you involved in the
18 formation of that task force?

19 A. We were. I was.

20 Q. When was that formed?

21 A. I want to say in 2013 at
22 some point. It was a amalgam of a
23 variety of different committees that had
24 been involved. Regulatory affairs

1 committee, federal government affairs
2 committee, individuals, and then to
3 basically brainstorm some suggestions for
4 additional things that we could do to
5 continue to move forward on addressing
6 suspicious orders and improving
7 interaction with the DEA.

8 Q. So that task force is an
9 outcrop of some of the types of
10 discussions that you had in Exhibit 34?

11 A. Yeah. It's not specifically
12 referenced here. But yeah, it's just an
13 ongoing discussion and dialogue with the
14 membership about what we can do to
15 improve.

16 Q. Who was on that task force
17 as far as the HDA's distributor members?

18 A. So if you look at the top,
19 AmerisourceBergen, Cardinal Health,
20 Mutual Drug, Smith Drug, HD Smith, Henry
21 Schein, I think was at one point
22 involved.

23 Q. McKesson?

24 A. McKesson, sorry, yes. And

1 then we had a -- after we had engaged
2 APCO at the time there, they came and
3 participated.

4 Q. And so you had regular
5 meetings with this task force?

6 A. This -- I believe this task
7 force met once.

8 Q. Okay. And so this is a list
9 of action items that came out of the task
10 force meeting?

11 A. Recommendations, yes.

12 Q. Okay. And then the attached
13 document, summary of recommendations?

14 A. Right.

15 Q. From December 11, 2013, task
16 force meeting. That's a summary of the
17 items that the group came up with that
18 you could move forward with?

19 MR. WEINSTEIN: Objection to
20 form.

21 THE WITNESS: Yes.

22 Sorry.

23 Yes, with the -- the
24 specific action items highlighted.

1 BY MR. PIFKO:

2 Q. And you typed this up?

3 A. I believe I typed the
4 e-mail, and then the notes were kind of
5 probably a shared product of the
6 government affairs staff that
7 participated.

8 Q. Okay. But you ultimately
9 sent it out to everybody?

10 A. I sent it out, yes.

11 Q. Did you have an official
12 title or role with this task force, like
13 chairman or --

14 A. No.

15 Q. -- coordinator?

16 A. No, there was -- and again
17 it was an ad hoc group of various
18 members. It was set up to do one thing,
19 and this was the one thing.

20 Q. So going to the attachment,
21 CAH_MDL2804_01110714. Are you there?

22 A. I am.

23 Q. So Item 2 is, "Address
24 specific challenges and interactions

1 with" -- "with DEA."

2 Do you see that?

3 A. Yes.

4 Q. So you have this broken out
5 into different types of communications
6 like one with the media, public
7 officials, another with DEA, and another
8 with a branding campaign; is that
9 correct?

10 MR. WEINSTEIN: Objection to
11 form.

12 THE WITNESS: Yeah.

13 BY MR. PIFKO:

14 Q. Okay. Sorry, I pointed you
15 to 2, but I want to ask you about 1 for a
16 minute.

17 A. Okay.

18 Q. So in 1, there's a
19 discussion about joining with various
20 other industry groups?

21 A. Mm-hmm.

22 Q. Is that correct?

23 A. Yes.

24 Q. Okay. What's the Alliance

1 to Prevent Abuse of Medicines?

2 A. That was a coalition that
3 formed, I want to say in about 2012, to
4 address abuse issues, kind of across the
5 supply chain. So they had formed -- the
6 American Medical Association, the members
7 that were listed there were participants.
8 Cardinal Health had suggested possibly
9 including HDA as a member, because other
10 associations were involved.

11 THE VIDEOGRAPHER:

12 Mr. Kelly, you keep hitting --

13 THE WITNESS: I'm sorry.

14 BY MR. PIFKO:

15 Q. So then Item 2 says,
16 "Address specific challenges and
17 interactions with DEA."

18 Do you see that?

19 A. I do.

20 Q. Then it says, "Issue
21 statement of support for Marino/Blackburn
22 legislation when introduced."

23 Do you see that?

24 A. I do.

1 Q. Okay. So that hadn't yet
2 been introduced at this time?

3 A. I don't know the specific
4 introduction date, but I would deduce
5 from this that obviously it had not.

6 Q. Okay. Was the -- that
7 legislation drafted out of the HDMA?

8 A. No. I believe
9 Mr. Blackburn -- or I'm sorry, Mr. Marino
10 was moving forward with that issue, had
11 requested feedback from a variety of
12 constituencies, and was in the process of
13 kind of fleshing it out.

14 Q. When was the first time you
15 became aware of that bill or that
16 legislation?

17 A. It -- it might have been at
18 this -- at this meeting. One of our
19 member companies had been contacted by
20 Mr. Marino about participating in the --
21 in the kind of the general drafting
22 process of -- of that bill. And it was
23 suggested that we -- we work with -- or
24 HDA work with Congressman Marino and

1 Congresswoman Blackburn.

2 Q. Do you know which member
3 company it was?

4 A. It was Cardinal.

5 Q. Okay. So Mr. Marino had
6 reached out to Cardinal and asked them to
7 assist in drafting this bill?

8 A. That's my understanding.

9 Q. And then they reached out to
10 you and asked HDA to participate?

11 A. They did.

12 Q. And did HDA end up providing
13 any drafting on the bill?

14 A. We provided feedback on
15 drafts that they -- they would -- that
16 they would basically share drafts with
17 us. I don't know if it was in advance of
18 the actual introduction. But they go
19 through iterative processes of kind of
20 taking comments and providing subsequent
21 drafts. We did participate in that
22 process.

23 Q. Do you know who -- who
24 specifically at Cardinal did you interact

1 with on that issue?

2 MS. WICHT: Objection to
3 form.

4 THE WITNESS: Connie
5 Woodburn was the government
6 affairs person for Cardinal at the
7 time.

8 BY MR. PIFKO:

9 Q. Okay. But did you interact
10 with anyone else from Cardinal?

11 A. Not specifically with regard
12 to this.

13 Q. Okay. Did -- do you -- do
14 you know, were there other people who
15 maybe you didn't talk to but that would
16 have been copied on e-mails or there are
17 things would have been forwarded from
18 Cardinal with respect to the
19 Marino/Blackburn bill?

20 MS. WICHT: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form, foundation, scope.

24 THE WITNESS: I can't say

1 for certain.

2 BY MR. PIFKO:

3 Q. Do you know if Linden Barber
4 was involved in the Marino/Blackburn
5 bill?

6 MR. WEINSTEIN: Same
7 objections.

8 MS. WICHT: Object to form.

9 THE WITNESS: I don't know
10 initially. It was a multi-year
11 process.

12 BY MR. PIFKO:

13 Q. Do you know if any other HDA
14 distributor members were involved in
15 discussions with Marino at that time
16 concerning the bill?

17 MS. WICHT: Objection to
18 form.

19 MR. WEINSTEIN: Objection to
20 form, foundation, scope.

21 THE WITNESS: At that time I
22 do not.

23 BY MR. PIFKO:

24 Q. How about later?

1 MS. WICHT: Objection to
2 form.

3 MR. WEINSTEIN: Same
4 objections.

5 THE WITNESS: Well, as soon
6 as -- as soon as HDA basically
7 endorsed the -- the initiative, I
8 think the entire membership was
9 supportive of the -- the prospect
10 of that legislation.

11 BY MR. PIFKO:

12 Q. Okay. And obviously the
13 entire member -- or the -- the members we
14 just discussed here having been involved
15 with this drug diversion task force all
16 knew about it because it was discussed at
17 this meeting, correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 MS. WICHT: Foundation.

21 THE WITNESS: Correct.

22 BY MR. PIFKO:

23 Q. So it says here, "This
24 legislation would establish definitions

1 and parameters for specific provisions in
2 the Controlled Substances Act pertaining
3 threats to 'public health and safety' and
4 'imminent danger.'

5 "In addition, this
6 legislation would allow DEA registrants
7 the opportunity to submit a corrective
8 action plan to address specific concerns
9 that could otherwise lead to the
10 suspension or revocation of a
11 registration."

12 Did I read that correctly?

13 A. You did.

14 Q. Is that consistent with your
15 understanding about what this bill would
16 do or legislation would do?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: It is. There
20 was another provision ultimately
21 of the bill. But it was a
22 draft -- a report from the
23 government on the effectiveness of
24 the government's efforts to

1 address prescription drug abuse
2 and diversion.

3 BY MR. PIFKO:

4 Q. Okay. So it's your
5 understanding there were changes to the
6 requirements for suspending a
7 registration, and there was another
8 component to the legislation that
9 involved a report?

10 MR. WEINSTEIN: Objection to
11 form.

12 BY MR. PIFKO:

13 Q. Is that correct?

14 MR. WEINSTEIN: Same
15 objection.

16 THE WITNESS: So, basically
17 the crux of it was to provide a
18 definition for the threshold for
19 immediate suspension orders.
20 Which was not anywhere in law.
21 The immediate -- the immediate --
22 imminent danger was not defined.
23 And so we basically sought to
24 establish a threshold for what

1 constitutes imminent danger.

2 BY MR. PIFKO:

3 Q. If we go to the next page of
4 your notes. Another action item that
5 this task force was working on was Item
6 D, "Anticipate and develop responses to
7 Marino/Blackburn opponents"?

8 A. I see that.

9 Q. That was something that this
10 task force was working on, correct?

11 A. Well, again, it wasn't one
12 of the action items. But it was -- it
13 basically was something that we
14 discussed. It was, you know, how do
15 we -- how do we explain what this does if
16 people are concerned that it's somehow
17 diminishing the capacity of the DEA.

18 Q. Item 3 here is, "Engage in
19 initial HDMA public relations branding
20 campaign."

21 Do you see that?

22 A. I do.

23 Q. Item C there says, "Utilize
24 material prepared by APCO to begin

1 targeted media outreach."

2 Do you see that?

3 A. I do.

4 Q. That's the material that
5 includes the crisis playbook, correct?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: Again, I'm not
9 exactly sure. The crisis playbook
10 was never -- it was a draft format
11 that was never released. It was
12 never published. It was -- we
13 didn't do anything with it. But
14 that was a product that APCO did
15 provide us in their initial
16 engagement.

17 BY MR. PIFKO:

18 Q. Okay. And you shared that
19 product with the HDA's members, correct?

20 MS. CHARLES: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, I don't

1 recall. Our communications
2 department handled all that
3 interface with APCO.

4 BY MR. PIFKO:

5 Q. You wouldn't have any reason
6 to dispute that it was shared with
7 members?

8 MR. WEINSTEIN: Objection to
9 form.

10 MS. CHARLES: Objection to
11 form.

12 MS. ROLLINS: Objection to
13 form.

14 THE WITNESS: I can't say
15 one way or another.

16 BY MR. PIFKO:

17 Q. You would agree if it was
18 produced by one of the members in this
19 litigation, it must have been shared with
20 them obviously, right?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: Yes.
24

1 BY MR. PIFKO:

2 Q. I'm handing you what's been
3 marked Exhibit 36.

4 (Document marked for
5 identification as Exhibit
6 HDA-Kelly-36.)

7 BY MR. PIFKO:

8 Q. Take a moment to review that
9 and let me know when you're ready. For
10 the record, it's a single -- two-page
11 document, Bates-labeled HDA_MDL_000214864
12 through 4865.

13 A. Okay.

14 Q. This is an e-mail from
15 Kristen Freitas to Linden Barber.

16 Do you see that?

17 A. I do.

18 Q. And it says, "Manufacturer
19 issue with imminent danger definition."

20 Do you see that?

21 A. Yes.

22 Q. And it says, "We were
23 contacted by a manufacturer that has
24 concerns about the definition of imminent

1 danger. This manufacturer has reached
2 out to other manufacturers as well to
3 raise concerns."

4 Do you see that?

5 A. I do.

6 Q. Did I read that correctly?

7 A. You did.

8 Q. Okay. And then Kristen is
9 asking Linden to let her know thoughts on
10 the suggestions from these manufacturers,
11 agree?

12 A. Yes.

13 MR. WEINSTEIN: Objection to
14 form.

15 BY MR. PIFKO:

16 Q. Okay. And the suggested
17 changes from the manufacturer's attorney
18 are provided on the second page of this
19 document, correct?

20 A. Again, if this was attached
21 to the e-mail, then, yes, I would agree
22 that that includes -- was included in the
23 e-mail.

24 Q. Okay. And so, she

1 paraphrases comments from the
2 manufacturer's attorney in her e-mail to
3 Linden Barber. And she says, "My
4 suggested changes are" -- it basically
5 says that -- sorry, that, "The first
6 comment change could be ignored but the
7 second and third are, in my view,
8 critical to protect the interest of
9 virtually all DEA registrants, not just
10 manufacturers."

11 Do you see that?

12 A. Yes.

13 Q. Would you agree that at some
14 point the HDA also started working with
15 manufacturers and members of the Pain
16 Care Forum on the Marino/Blackburn bill?

17 MR. WEINSTEIN: Objection to
18 form.

19 MS. MACKAY: And foundation.

20 THE WITNESS: Again, I don't
21 know that we ever worked with the
22 Pain Care Forum on this bill. I
23 know that the manufacturers were
24 working with Senator Hatch's

1 office. And the concerns that
2 were expressing to Senator Hatch
3 we being expressed by Senator
4 Hatch's staff to us. And we were
5 asked to rectify those concerns
6 moving forward.

7 BY MR. PIFKO:

8 Q. The legislation from Senator
9 Hatch was the same?

10 MR. WEINSTEIN: Objection to
11 form.

12 THE WITNESS: The -- I'm
13 sorry?

14 BY MR. PIFKO:

15 Q. It's the same legislation,
16 you're dealing with Senator Hatch --

17 A. It was -- yes, it was -- it
18 was the senate version of the
19 Marino/Blackburn bill, Senate Bill 483,
20 or what became Senate Bill 483.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-37.)
24

1 BY MR. PIFKO:

2 Q. I'm handing you what's
3 marked as Exhibit 37. It's a two-page
4 document, Bates-labeled HDA_MDL_000081283
5 through 284.

6 Take a minute to review it
7 and let me know when you're done.

8 A. Okay.

9 Q. Who is Jewelyn Cosgrove?

10 A. She works in the federal
11 government affairs department at HDA.

12 Q. Is she someone that reports
13 to you?

14 A. She reports to Kristen
15 Freitas.

16 Q. And she --

17 A. Ultimately under my
18 department, yes.

19 Q. Okay. So she writes to Burt
20 Rosen of Purdue and asks for him to share
21 this with the Pain Care Forum.

22 Do you see that?

23 A. Yes.

24 Q. And it's -- the subject is,

1 "Re-introduction of Ensuring Patient
2 Access and Effective Drug Enforcement
3 Act." That's the Marino/Blackburn bill,
4 correct?

5 A. Yes.

6 Q. Okay. And he then forwards
7 it to the members of the Pain Care Forum
8 on the first page.

9 Do you see that?

10 A. I do.

11 Q. And it's got attachments
12 that are summaries of the bill.

13 Do you see that on the
14 header?

15 A. I do.

16 Q. Okay. Oh, and she then
17 says, "Last year, we worked with a number
18 of you on a letter of support for
19 legislation introduced in the house and
20 senate establishing an enforcement
21 escalation procedure."

22 Do you see that?

23 A. Yes.

24 Q. I'm on the second page of

1 that.

2 A. Yes, yes, yes, yes.

3 Q. "And then for reference the
4 two bills were the Ensuring Patient
5 Access and Effective Drug Enforcement Act
6 in the House, Representatives Marino,
7 Blackburn, Welch, Chu; and the Regulatory
8 Transparency, Patient Access, and
9 Effective Drug Enforcement Act in the
10 Senate from Senators Hatch and
11 Whitehouse."

12 Do you see that?

13 A. Yes.

14 Q. And then later on the
15 bottom, "With the process moving quickly,
16 we would like to ask those of you who
17 signed the senate letter of support from
18 patient groups last year to consider
19 supporting the House legislation."

20 Do you see that?

21 A. I do.

22 Q. I'm handing you what's
23 marked as Exhibit 38.

24 (Document marked for

1 identification as Exhibit

2 HDA-Kelly-38.)

3 BY MR. PIFKO:

4 Q. Take a moment to review
5 Exhibit 38. And let me know when you're
6 done.

7 For the record, Exhibit 38
8 is a four-page document Bates-labeled
9 HDA_MDL_000081651 through 81654.

10 A. Okay.

11 Q. This just confirms in
12 response to Jewelyn's request that the
13 Pain Care Forum support the bill. Burt
14 Rosen from Purdue then sends her back the
15 letter signed and -- with their
16 endorsement. Agree?

17 UNIDENTIFIED LAWYER:

18 Objection. Form.

19 MR. WEINSTEIN: Objection to
20 form.

21 MS. MACKAY: Objection to
22 form.

23 THE WITNESS: Yes.

24 BY MR. PIFKO:

1 Q. I'm handing you what's
2 marked as Exhibit 39.

3 (Document marked for
4 identification as Exhibit
5 HDA-Kelly-39.)

6 BY MR. PIFKO:

7 Q. This document is not
8 Bates-labeled. We printed it from HDA's
9 website. Take a moment to review it.

10 For the record, it's a
11 document that is identified on the first
12 page as "Statement from John Gray,
13 President and CEO, Healthcare
14 Distribution Management Association For
15 the U.S. House of Representatives Energy
16 and Commerce Committee, Subcommittee on
17 Health," dated April 7, 2014. It's a
18 five-page document.

19 Have you seen this before?

20 A. I have.

21 Q. Did you assist in preparing
22 this testimony?

23 A. I did.

24 Q. And this is testimony that

1 Mr. Gray provided for the House of
2 Representatives energy and commerce
3 committee subcommittee on health --

4 A. It --

5 Q. -- from April 7, 2014?

6 A. It is.

7 Q. These are statements that he
8 made before that committee?

9 A. This is the written
10 statement. I don't know how much it
11 deviated from the oral statement.

12 Q. Okay. And you participated
13 in -- in writing this?

14 A. I helped to prepare it, yes.

15 Q. Okay. Anyone else?

16 A. The whole government affairs
17 team. Probably our communication team as
18 well.

19 Q. And in this he's discussing,
20 the Marino/Blackburn bill, correct?

21 A. Yes.

22 Q. Second sentence, "Thank you
23 for the opportunity to discuss with the
24 subcommittee important legislation

1 introduced by Representatives Blackburn
2 and Marino, the Ensuring Patient Access
3 and Effective Drug Enforcement Act of
4 2014," correct?

5 A. Yes.

6 Q. Then the next paragraph,
7 second sentence, he says, "Our industry's
8 primary mission is to operate the safest
9 and most secure and efficient supply
10 chain in the world."

11 Agree with that statement?

12 A. I do.

13 Q. "As part of this mission,
14 the pharmaceutical industry is committed
15 to addressing the serious national
16 epidemic of prescription drug abuse."

17 Do you see that?

18 A. I do.

19 MR. WEINSTEIN: You missed
20 the word "distribution" in there,
21 you missed.

22 MR. PIFKO: Sorry. I'll
23 read it again for the record.

24 BY MR. PIFKO:

1 Q. To be clear, so Mr. Gray
2 testified before this committee and said
3 that "the pharmaceutical distribution
4 industry is committed to addressing the
5 serious national epidemic of prescription
6 drug abuse," correct?

7 A. Yes.

8 Q. Next paragraph. Mr. Gray
9 also told the committee, "HDMA's members
10 are committed to working proactively with
11 DEA," correct?

12 A. Yes.

13 Q. Page 2 of the testimony. He
14 says, "This is one of the reasons" --
15 second full paragraph. "This is one of
16 the reasons why HDMA supports HR 4069."

17 That's the Marino/Blackburn
18 bill, correct?

19 A. Yes.

20 Q. He says this -- he told the
21 committee, "This legislation is a timely
22 and thoughtful approach to addressing the
23 prescription drug epidemic," correct?

24 A. Yes.

1 Q. And he said, "We will
2 believe it will foster greater
3 collaboration, communication and
4 transparency between" -- "between
5 industry stakeholders and regulators,
6 especially the DEA," correct?

7 A. Correct.

8 Q. And then in the next
9 paragraph he talks about establishing a
10 collaborative working relationship with
11 the DEA.

12 Do you see that?

13 A. Yes.

14 Q. And he provided that
15 testimony to the subcommittee as well,
16 correct?

17 A. Yes.

18 (Document marked for
19 identification as Exhibit
20 HDA-Kelly-40.)

21 BY MR. PIFKO:

22 Q. I'm handing you what's
23 marked as Exhibit 40. It's an e-mail
24 from you to Ann Berkey of McKesson,

1 dated -- or dated March 24, 2014.

2 Bates-labeled MCKMDL00651560 to 651563.

3 Take a moment to review that
4 and let me know when you're done.

5 A. Okay.

6 Q. So, on the first page
7 there's an e-mail here from you to Ann
8 Berkley. Who is Ann Berkley?

9 A. Ann Berkey was --

10 Q. Sorry.

11 A. -- at the time the head of
12 the government affairs operation at
13 McKesson.

14 Q. Okay. And you also reach
15 out to Connie Woodburn and Rita Norton?

16 A. Right. The only -- they are
17 the only company government affairs
18 representatives from any of our member
19 companies.

20 Q. Okay. So you are reaching
21 out to McKesson, Cardinal, and
22 AmerisourceBergen, correct?

23 A. Right.

24 Q. And at the bottom you say,

1 "It looks like we have some challenges
2 finding a time that worked for everyone.
3 Can we possibly do a quick call for
4 today? If not, I can fill everyone in
5 via e-mail regarding a discussion the
6 executive committee had last week on the
7 topic of drug abuse diversion
8 specifically with regard to the
9 Marino/Blackburn legislation."

10 Do you see that?

11 A. I do.

12 Q. Okay. So you sought to
13 update them with -- with respect to a
14 discussion the executive committee had on
15 the Marino/Blackburn legislation,
16 correct?

17 A. Yes, yes, that's what this
18 indicates.

19 Q. Okay. And then in the
20 e-mail on the top, Ann, you write to Ann.
21 She apparently said she was on a plane,
22 and then you write to her and say, about
23 halfway down that e-mail, "John sent a
24 memo, attached."

1 Do you see that?

2 A. Yes.

3 Q. "To executive committee
4 members on Friday."

5 Do you see that?

6 A. I do.

7 Q. "Regarding next steps on the
8 Marino/Blackburn legislation."

9 Do you see that?

10 A. Yes.

11 Q. And then you've got the --
12 the memos attached here to this e-mail?

13 A. Mm-hmm.

14 Q. It's entitled, "Status of
15 HR 4069."

16 Yes?

17 A. Yes.

18 Q. Who put this memo together?
19 John Gray?

20 A. It was probably prepared by
21 the government affairs department.

22 Q. Okay. Did you have an
23 involvement in putting this together?

24 A. I don't know that I'd wrote

1 it. But I probably saw before it was
2 submitted to the executive committee.

3 Q. Okay. I want to turn your
4 attention to the second page of the memo,
5 third page of Exhibit 40. There's a
6 heading "DEA."

7 Do you see that?

8 A. I do.

9 Q. "In conversations with
10 numerous HDMA member companies and select
11 Hill staff, as well as Al Santos,
12 recently retired from DEA office of
13 diversion control, it is our
14 understanding that DEA is very concerned
15 with this legislation 'tying the agencies
16 hands' to actively and aggressively
17 address diversion and compliance with the
18 CSA."

19 Do you see that?

20 A. I do.

21 Q. Did I read that correctly?

22 A. You read it verbatim.

23 Q. Okay. It was HDA and its
24 members' understanding that DEA felt that

1 this legislation would tie the agency's
2 hand?

3 MR. WEINSTEIN: Objection to
4 form. Foundation.

5 THE WITNESS: Yeah, this
6 version -- again, this was two
7 years before the bill was passed,
8 and it was changed multiple times
9 afterwards with their input and
10 feedback.

11 So initial versions were,
12 yes, opposed by the agency.

13 BY MR. PIFKO:

14 Q. And then it says,
15 "Essentially, the DEA is categorically
16 opposed to the provisions in the
17 legislation to mandate definitions of
18 imminent danger and consistent with
19 public health and safety."

20 Do you see that?

21 A. I do.

22 Q. It was your understanding
23 that DEA was categorically opposed to
24 those provisions?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: They were --
4 at the time they were concerned
5 that providing any definition of
6 those terms would somehow require
7 them to satisfy criteria that they
8 didn't have to meet at that point
9 in time.

10 BY MR. PIFKO:

11 Q. And then it says, "They were
12 also categorically opposed to
13 implementing corrective action plans as
14 well."

15 Correct?

16 A. Yes.

17 Q. "And they were categorically
18 opposed to force the agency to
19 participate in a stakeholder working
20 group."

21 Correct?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: That's what it

1 says, yes.

2 BY MR. PIFKO:

3 Q. Was that your understanding
4 that they were -- they were categorically
5 opposed to that?

6 A. Again, I --

7 MR. WEINSTEIN: Objection to
8 form.

9 THE WITNESS: I don't know
10 what -- what categorically they
11 were more opposed to than not.
12 But they were opposed to
13 essentially most of that --

14 BY MR. PIFKO:

15 Q. Those future --

16 A. -- most of those issues,
17 yes.

18 Q. And the last page of the
19 memo there's some other bullet points.
20 One of them is -- the top one on the last
21 page. It says, "DEA is adamantly opposed
22 to this legislation and has made their
23 position known to Hill staff as well as
24 to some industry representatives."

1 Do you see that?

2 A. Yes.

3 Q. It was your understanding
4 that they were adamantly opposed to
5 legislation at that time?

6 A. To that version of the bill
7 in 2014, which is two years before the
8 final bill was passed, yes.

9 Q. Did the final bill have the
10 definition of imminent danger?

11 A. It did.

12 Q. Did it have the corrective
13 action plan?

14 A. It did.

15 Q. Did it mandate the DEA to
16 participate in a stakeholder working
17 group?

18 A. It did.

19 Q. Did it add the "consistent
20 with public health and safety" language?

21 A. I don't know if the specific
22 language was in there. I'm happy to look
23 at the final version of the bill and tell
24 you, yes. And DEA did not oppose the

1 final version of that legislation.

2 MR. WEINSTEIN: We've been
3 going about an hour.

4 MR. PIFKO: We'll take a
5 break in about two seconds.

6 BY MR. PIFKO:

7 Q. I want to turn your
8 attention back to Exhibit 31 to Page 11
9 and 12. I want to direct you to language
10 on Page 12, but 11 tells you that this
11 was a discussion that occurred at the
12 September 28, 2015, board of directors
13 meeting. Turn to Page 12. Tell me when
14 you're ready.

15 A. Okay.

16 Q. During this September 28,
17 2015, board of directors meeting,
18 "President Gray noted HDMA executive
19 committee had discussed and agreed to
20 prioritize objectives on prescription
21 drug abuse in the following order: Item
22 Number 1, exhaust all efforts to secure
23 passage of S.483."

24 Do you see that?

1 A. On -- which page are you on?

2 Q. 12.

3 A. Oh, yes. Okay, I see it.

4 Q. Did I read that correctly?

5 A. "Exhaust all efforts to
6 secure passage of S.483." Yes.

7 Q. So S.483 is the final
8 version that got passed?

9 A. It was, yes, the bill that
10 got passed by the senate and approved
11 unanimously both -- in both chambers and
12 signed by President Obama.

13 MR. PIFKO: Okay. We can
14 take a break.

15 THE VIDEOGRAPHER: The time
16 is 3:51 p.m. We are going off the
17 record.

18 (Short break.)

19 THE VIDEOGRAPHER: The time
20 is 4:11 p.m. We are back on the
21 record.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-41.)

1 BY MR. PIFKO:

2 Q. I'm handing you what's been
3 marked Exhibit 41.

4 For the record it's a series
5 of e-mails, the recent one dated Monday,
6 May 1st, 2017, from Matt DiLoreto to Beth
7 Mitchell. Bates-labeled
8 HDA_MDL_000214979 through 214982.

9 On the first page of this
10 document, Beth Mitchell from
11 AmerisourceBergen writes to Matt DiLoreto
12 on Monday, May 1st, 2017. She says, "Hi,
13 Matt. Have you been able to find
14 anything? Any state bills or approaches
15 we have ever been able to say yes, we
16 support this as an effort to address
17 opioid abuse?"

18 Do you see that?

19 A. I do.

20 Q. Matt writes back, and says,
21 "Sorry for the delay on this project, but
22 I was really hoping to find something."

23 Do you see that?

24 A. Yes.

1 Q. And then at the bottom of
2 his e-mail there on the first page, he
3 says, "Bottom line is I talked with both
4 Patrick and Liz, and they cannot recall
5 any time that we openly and publicly
6 supported an opioid abuse prevention
7 measure."

8 Do you see that?

9 A. I do.

10 Q. Is that a correct statement?

11 A. That's not a correct
12 statement.

13 Q. What opioid abuse prevention
14 measures has HDA supported?

15 A. A significant number of
16 provisions across the -- I mean, at the
17 state level, it's harder because we're
18 much more -- we have a smaller group, and
19 it's difficult to be kind of proactive at
20 the state level. We have to be more
21 reactive than not. So allocating
22 resources at the state level can be a
23 challenge.

24 So we tend to go where we've

1 got the most pressure and allocate
2 resources there.

3 But at the federal level and
4 with the media, we've done a lot of work
5 with coalitions. We did our practical
6 solutions suggestions. We worked with
7 various state organizations, NADDI,
8 National Association of Boards of
9 Pharmacy, National Community Pharmacists
10 Association to support initiatives to
11 address prescription drug abuse and
12 diversion with them.

13 Whether or not we were able
14 to support a particular bill in a state,
15 that's going to be probably a little bit
16 more difficult given the resource
17 challenges we have. But as far as
18 activities and publicly supporting opioid
19 prevention measures, we absolutely have
20 been very involved, very engaged on that
21 issue.

22 Q. Okay. But with respect to
23 legislation or bills, is it a true
24 statement that HDA has never publicly

1 supported an opioid abuse prevention
2 measure?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: I can't --
6 again, one doesn't immediately
7 jump to mind. That's not to say
8 that there are bills out there
9 that had passed that just maybe we
10 didn't even think were opioid
11 abuse prevention measures. But
12 I -- I can't -- again, don't --
13 don't have one that I can
14 immediately point to.

15 I can -- you know what, let
16 me clarify that. There are bills
17 with regard to suspicious order
18 monitoring. We've been requested
19 to have -- support state
20 regulatory authorities access to
21 suspicious order monitoring and
22 ARCOS data, that we're happy to
23 work with in the State of
24 Virginia, State of West Virginia,

1 State of Tennessee, all requested
2 that we provide opioid
3 distribution information to them.
4 We complied and said as long as,
5 you know, it's duplicative of what
6 we're sending to DEA, we're happy
7 to do that.

8 BY MR. PIFKO:

9 Q. When you say opioid
10 distribution information, what do you
11 mean?

12 A. ARCOS data.

13 Q. Okay.

14 A. ARCOS data and suspicious
15 order monitoring reports.

16 Q. Okay. But that's not any
17 legislation or bills, correct?

18 A. It's not.

19 Q. I'm handing you what's
20 marked as Exhibit 42.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-42.)

24 BY MR. PIFKO:

1 Q. It's another e-mails with
2 agenda and summary of meetings from Anita
3 Ducca back in 2008. Bates-labeled
4 CAH_MDL2804_01364288 through 300.

5 This is a lengthy document,
6 but I just want to ask you about one
7 provision in here.

8 A. Is there a specific
9 provision?

10 Q. Yeah, I was waiting for you
11 to tell me you were ready.

12 A. Okay. I'm ready.

13 Q. So the -- on the first page
14 it's an e-mail from Anita Ducca, another
15 one of her reminders about conference
16 calls. And she's attaching a summary of
17 a regulatory affairs meeting that
18 occurred on July 17, 2008. It's five
19 pages in.

20 Do you see that?

21 A. Yes.

22 Q. Okay. Do you have any
23 reason to dispute that these are accurate
24 notes of the meeting?

1 MR. WEINSTEIN: Objection to
2 form. Foundation.

3 THE WITNESS: I do not. I
4 can't say for certain. I was not
5 HDA at the time. But I will take
6 it at face value that they were
7 accurate that they were sent out
8 by Anita.

9 BY MR. PIFKO:

10 Q. You understand that you --
11 one of your designations here as a
12 30(b)(6) witness for -- for HDA is
13 committee meetings --

14 A. Yes.

15 Q. -- concerning opioids and
16 the substance of those meetings, correct?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: I do, yes.

20 BY MR. PIFKO:

21 Q. Okay. And so you don't have
22 any reason to dispute that these are
23 accurate notes?

24 MR. WEINSTEIN: Objection to

1 form.

2 THE WITNESS: I have no
3 reason to dispute that these are
4 accurate notes.

5 BY MR. PIFKO:

6 Q. Okay. So I want to direct
7 your attention to Page 3 of the notes,
8 which is CAH_MDL2804_01364294. Tell me
9 when you're there.

10 A. I see it.

11 Q. Okay. There's a section
12 here, it says, "Proposed rule on quotas."
13 Do you see that?

14 A. Yeah.

15 Q. Okay. Does DEA participate
16 in these meetings from time to time?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: Participate in
20 what meetings?

21 BY MR. PIFKO:

22 Q. The regulatory affairs
23 meetings.

24 A. They are invited guests in

1 some instances.

2 Q. Okay. On the first page of
3 the notes it says, "Four staff members of
4 the DEA join the meeting at approximately
5 9:15. Mark Caverly explained that since
6 it was an election year, DEA expected a
7 slowdown in new initiatives, and the
8 Office of Management and Budget has told
9 DEA staff not to submit new major
10 rulemakings."

11 Do you see that?

12 A. No. What page are you?

13 Q. First page of the notes.
14 Fifth page of the document. 1364292.

15 A. Okay.

16 Q. Do you see that?

17 A. Four members, yes, okay.

18 I'm -- I'm with you.

19 Q. So the four members from DEA
20 joined the meeting, correct?

21 A. Correct.

22 Q. And then the -- the members
23 of the regulatory affairs committee would
24 have participated as well, correct?

1 A. I believe so, yes.

2 Q. It says, "The agenda and
3 list of attendees and guests are
4 attached"?

5 A. Okay.

6 Q. Do you see that, it says
7 that on the first page?

8 A. Yes.

9 Q. And then we see that HDA
10 members present, if you go to Page 5 of
11 the notes, 1364296?

12 A. I do.

13 Q. Okay. It's got Steve
14 Reardon from Cardinal, Mark Hartman from
15 Cardinal, Gary Hilliard from McKesson,
16 Steve Mays from AmerisourceBergen.

17 Do you see that?

18 A. And Mike Shoneff from
19 Valley, and Roger Peters, and Brad Pine
20 and Mike DeBello and Sergio Tejeda.

21 Q. Okay. And then it's got the
22 DEA staff that attended as well?

23 A. Yes.

24 Q. And HDMA staff, correct?

1 A. Yes.

2 Q. Okay. So going -- sorry,
3 going back to the third page of the
4 notes. 1364294. Let me know when you're
5 there.

6 A. I'm there.

7 Q. It says, "Proposed rule on
8 quotas for Schedule I and Schedule II
9 substances. DEA discussed the reduction
10 in illicit internet purchases and its
11 impact on decisions on manufacturing
12 quota sizes. We pointed out the
13 incongruity of DEA's increases in quota
14 sizes and the expectation that
15 distributors will cut back on
16 distribution."

17 Do you see that?

18 A. I do.

19 Q. Do you have any reason to
20 dispute that this was discussed at the
21 meeting?

22 A. I do not.

23 Q. So to your knowledge, this
24 was discussed at the meeting?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: To my
4 knowledge it was discussed at the
5 meeting.

6 (Document marked for
7 identification as Exhibit
8 HDA-Kelly-43.)

9 BY MR. PIFKO:

10 Q. I'm handing you what's
11 marked as Exhibit 43. It is a three-page
12 document, Bates-labeled HDA_MDL_000088099
13 through 88101.

14 Take a minute to review this
15 and let me know when you're done.

16 A. Okay.

17 Q. You are part of the e-mail
18 at the bottom here from John Parker to a
19 bunch of people including you, do you see
20 that, dated February 8, 2012?

21 A. Yes.

22 Q. It says, "New DEA
23 talking" -- "TPs," talking points,
24 correct?

1 A. Yes.

2 Q. "Attached are the revised
3 DEA talking points. I essentially kept
4 one of Cardinal's three bullets with a
5 few modifications."

6 Did I read that correctly?

7 A. You did.

8 Q. So HDA worked with members
9 of the executive committee to draft
10 talking points concerning the District
11 Court's TRO against the DEA's suspension
12 order of Cardinal Health Lakeland
13 distribution center, correct?

14 MS. ROLLINS: Objection to
15 form.

16 MS. WICHT: Objection.

17 THE WITNESS: That's what
18 the first bullet point says, yes.

19 BY MR. PIFKO:

20 Q. And the executive committee
21 worked to draft these; is that correct?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, I don't

1 think the executive committee
2 drafted them. I think they were
3 probably shared with the executive
4 committee. And if they had
5 comments or provided feedback,
6 that was incorporated.

7 BY MR. PIFKO:

8 Q. Okay. Well, at the top of
9 this e-mail, John Gray writes to David
10 Neu from AmerisourceBergen, and says,
11 "For our 12:30 call, attached is the
12 latest version based on input from the
13 rest of the executive committee."

14 Do you see that?

15 A. Yes.

16 Q. So this has had input from
17 everybody but AmerisourceBergen at this
18 point, correct?

19 MR. WEINSTEIN: Objection to
20 form.

21 THE WITNESS: That's what it
22 says, yes.

23 BY MR. PIFKO:

24 Q. Is that your understanding

1 of --

2 A. That is my understanding.

3 Q. -- what happened?

4 A. Again, I don't recall this
5 particular document. But I will not
6 dispute what the e-mail says.

7 Q. Do you know if
8 AmerisourceBergen ultimately approved the
9 talking points?

10 A. I do not.

11 Q. What were these talking
12 points to be used for?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: Again, I don't
16 know specifically what these were
17 developed to address. Possibly
18 media coverage of the case
19 referenced in the first bullet
20 point.

21 BY MR. PIFKO:

22 Q. In the first bullet point,
23 it says, "HDMA is pleased that the
24 District Court granted the TRO against

1 the DEA," correct?

2 A. That's what it says, yes.

3 Q. And, "It allows Cardinal
4 Health to resume shipments of controlled
5 substances," correct? Second bullet
6 point says that?

7 A. Yes. That's what it says.

8 Q. Was this put on HDA's
9 website?

10 A. I do not know. It says at
11 the top, this is for internal use only,
12 do not distribute. So I would imagine it
13 did not make it to --

14 Q. Okay. Maybe some other
15 version? In your experience would
16 something like this be put on their -- on
17 the website?

18 MR. WEINSTEIN: Objection to
19 form.

20 THE WITNESS: Again,
21 specific talking points wouldn't
22 be put on the website. It would
23 be more, you know, kind of
24 policies, papers or statements or

1 comments that were submitted.

2 Talking points are generally
3 internal documents for purposes of
4 discussions either on the Hill or
5 with the media.

6 BY MR. PIFKO:

7 Q. Okay. So these could have
8 been used by your staff in talking to
9 members of the Hill?

10 A. They could have been.

11 MS. ROLLINS: Objection to
12 form.

13 BY MR. PIFKO:

14 Q. To your knowledge were they
15 used for that?

16 A. I -- not to my knowledge. I
17 don't know. I can't say for certain one
18 way or another.

19 Q. So sitting here today you
20 don't have any recollection of how these
21 were used?

22 A. Again, it's 2012. I don't
23 recall.

24 Q. I'll have you look back at

1 Exhibit 31. It looks like this.

2 A. Yes.

3 Q. The first entry on February
4 16, 2012 --

5 (Brief interruption.)

6 THE VIDEOGRAPHER: Off the
7 record. 4:29 p.m.

8 (Brief pause.)

9 THE VIDEOGRAPHER: The time
10 is 4:33 p.m. We are back on the
11 record.

12 BY MR. PIFKO:

13 Q. All right. So we're looking
14 at Exhibit 31 at the first entry dated
15 February 16, 2012.

16 Do you see that?

17 A. Yes.

18 Q. So this is a summary of the
19 portions of the executive committee,
20 correct?

21 A. Yes.

22 Q. Of the executive committee
23 meeting. And so it says that HDMA met
24 with DEA staff. And then at the second

1 part of the entry, it says, "EC" --
2 that's executive committee, correct?

3 A. That's correct.

4 Q. -- "asked OFW" -- that's
5 Olsson Frank, the outside counsel,
6 correct?

7 A. Correct.

8 Q. -- "to prepare a draft
9 amicus brief in the Cardinal case."
10 Correct?

11 A. Correct.

12 Q. So it's your understanding
13 that the executive committee asked HDA's
14 outside counsel to prepare an amicus
15 brief for the Cardinal case in
16 February 2012, correct?

17 A. That's correct.

18 Q. I'm handing you what's
19 marked Exhibit 44.

20 (Document marked for
21 identification as Exhibit
22 HDA-Kelly-44.)

23 BY MR. PIFKO:

24 Q. For the record it's an

1 e-mail from John Gray. At the top
2 there's some other e-mails. The top
3 e-mail is dated Thursday, February 23rd,
4 2012. And the subject is, "Draft Amicus
5 Brief, Cardinal Health v. Holder."

6 It's Bates-labeled
7 HDA_MDL_000215212 through 215233.

8 Take a minute to review that
9 and let me know when you're done.

10 A. Okay.

11 Q. So at the bottom of this
12 e-mail, David Durkin is e-mailing to
13 Richard Frank a revised draft of the
14 brief, agree?

15 A. Yes.

16 Q. Then, Richard Frank forwards
17 it. Richard Frank is an attorney at
18 Olsson Frank, correct?

19 A. Correct.

20 Q. Outside counsel for HDA,
21 correct?

22 A. Correct.

23 Q. Okay. He forwards the draft
24 amicus brief to John Gray and you and

1 others in HDA, correct?

2 A. Correct.

3 Q. And he writes, "HDMA
4 colleagues, attached is the draft amicus
5 brief for your consideration. The
6 executive committee asked that this be
7 sent to them for approval or objection
8 prior to filing. We should also run it
9 by Cardinal's counsel."

10 Did I read that correctly?

11 A. You did.

12 Q. Okay. Do you recall
13 receiving that e-mail?

14 A. I'm obviously here on the
15 addressees. Yes.

16 Q. Okay. And then at the top
17 of this e-mail here, John Gray forwards
18 it to David Moody, and David Neu from
19 AmerisourceBergen correct?

20 A. Correct. David Moody was
21 North Carolina Mutual and the chairman of
22 the organization.

23 Q. Okay. Is it your
24 understanding that John Gray also

1 forwarded the draft to the other members
2 of the executive committee as well?

3 MR. WEINSTEIN: Objection to
4 form. Foundation.

5 THE WITNESS: Again, I would
6 deduce that based on the executive
7 committee request. But this is
8 sent to the chairman and vice
9 chairman.

10 BY MR. PIFKO:

11 Q. So he sends it to them and
12 says, "Attached is a draft amicus brief
13 that HDMA could file on behalf of our
14 membership in support of the Cardinal
15 case next week. I think it's an
16 excellent recitation of our issues with
17 DEA. However, I fear it may be too
18 aggressive in Section 3 at this point in
19 time."

20 Do you see that?

21 A. Yes, I can read that.

22 Q. Do you recall any
23 discussions about what specifically was
24 too aggressive in Section 3?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: I do not
4 recall specific concerns about the
5 aggressive Section 3.

6 BY MR. PIFKO:

7 Q. John Gray never shared that
8 information with you?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: Again, I don't
12 recall. They may have shared that
13 information, there may have been
14 discussion about it. I just don't
15 recall.

16 BY MR. PIFKO:

17 Q. I'm handing you what's been
18 marked Exhibit 45.

19 (Document marked for
20 identification as Exhibit
21 HDA-Kelly-45.)

22 BY MR. PIFKO:

23 Q. Series of e-mails concerning
24 the same subject to Cardinal v. Holder

1 amicus brief. It's Bates-labeled
2 HDA_MDL_000215970 through 215973.

3 Take a moment to review this
4 and let me know when you're done.

5 A. Okay.

6 Q. You ready?

7 So on the last page of this
8 document, which is the earliest of the
9 e-mail thread, David Durkin, he's outside
10 counsel for HDA, correct?

11 A. Correct.

12 Q. He is the one who authored
13 the amicus brief for the Cardinal v.
14 Holder case, correct?

15 A. Correct.

16 Q. He's writing to Doug
17 Farquhar -- am I saying that right?

18 A. Yes.

19 Q. Doug -- do you know who Doug
20 Farquhar is?

21 A. I believe he is an attorney
22 at Hyman Phelps.

23 Q. Okay. And he was outside
24 counsel for Cardinal Health in the

1 underlying litigation, correct?

2 A. I -- I think so, yes. I
3 can't recall specifically.

4 Q. So David Durkin is asking
5 him for thoughts on how to handle the
6 judge in that case on the first page.

7 Do you see that?

8 MR. WEINSTEIN: Objection to
9 form.

10 MS. WICHT: Objection to
11 form.

12 BY MR. PIFKO:

13 Q. Do you agree with that?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: I agree that
17 there is a question to Doug about
18 the handling of the case, yes.

19 BY MR. PIFKO:

20 Q. And handling of how the
21 judge is handling the matter?

22 A. Yes.

23 Q. And anything he -- he's
24 asking anything you want me to be aware

1 of with regard to how Judge Walton is
2 handling this matter?

3 A. That's what it says, yes.

4 Q. Okay. And Doug Farquhar
5 writes back. And then there is some
6 subsequent discussions.

7 And then on February 24,
8 2012, Doug writes to David Durkin copying
9 Linden Barber.

10 Do you see that?

11 A. Yes.

12 Q. Starts on the first page of
13 the document?

14 A. Yes, yes, yes, yes.

15 Q. And he says, "David, Linden
16 Barber and I have reviewed the amicus
17 brief and think it's really quite good.
18 Cardinal Health does, in fact, authorize
19 you to represent that we consent to your
20 motion for leave to file. We make the
21 following suggestions," and then there's
22 a page of suggestions, and then it goes
23 on to the next page with the suggestions.
24 Agree?

1 A. I agree.

2 Q. Linden Barber was inhouse
3 counsel for Cardinal Health at this
4 point?

5 MS. WICHT: Objection to
6 form. Foundation.

7 THE WITNESS: I think Linden
8 at this time was with Quarles &
9 Brady.

10 BY MR. PIFKO:

11 Q. He was outside counsel for
12 Cardinal at this point, correct -- is
13 that correct?

14 A. Again, I don't know what his
15 specific role, or relationship was. But
16 I think he was, yes, at one point in
17 time. I don't know when that -- when
18 that engagement began.

19 Q. Okay. And then you were
20 aware that Cardinal's outside counsel had
21 provided comments on this brief, because
22 then David Durkin forwards this to you
23 with the subject Cardinal's counsel's
24 comments on amicus brief on Monday,

1 February 27, 2012, correct?

2 A. Yes.

3 Q. And we -- you know, but I
4 don't know what's there, because it's
5 redacted, correct?

6 A. I don't recall either, but I
7 see that my name was on the e-mail.

8 (Document marked for
9 identification as Exhibit
10 HDA-Kelly-46.)

11 BY MR. PIFKO:

12 Q. I'm handing you what's
13 marked as Exhibit 46. For the record,
14 it's a three-page document Bates-labeled
15 HDA_MDL_000216300 through 216302.

16 The subject is the HDMA
17 amicus brief, Cardinal v. Holder, DC
18 Circuit. The most recent e-mail is dated
19 March 5, 2012.

20 A. Okay.

21 Q. The HDA couldn't have filed
22 this brief unless they got approval from
23 all the members of the executive
24 committee, correct?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: That's usually
4 the process. They try to get
5 consensus approval, yes.

6 BY MR. PIFKO:

7 Q. That's the process here as
8 well?

9 A. I believe so, yes.

10 Q. John Gray writes to the
11 members of the executive committee on
12 March 4, 2012. Do you see that, on the
13 bottom of the first page?

14 A. Yes.

15 Q. I have it right that he's
16 writing to the members of the executive
17 committee?

18 A. At the time, yes.

19 Q. Okay. And he's -- and that
20 includes AmerisourceBergen, McKesson, and
21 Cardinal Health, correct?

22 A. And HD Smith and Dakota Drug
23 and Smith Drug and North Carolina Mutual.

24 Q. Okay. And he says, "I

1 apologize for" -- "apologize for
2 interrupting your weekend. HDMA outside
3 counsel was informed today that the U.S.
4 Court of Appeals in Washington agreed
5 late Friday to stay the district court's
6 ruling last Wednesday lifting the TRO on
7 the DEA's immediate suspension order
8 against Cardinal Health.

9 "As such, HDMA counsel is
10 recommending that HDMA now file the
11 amicus brief prepared after our recent
12 executive committee to set forth HDMA's
13 overall industry concern."

14 Do you see that?

15 A. I do.

16 Q. Okay. Do I have that
17 correct?

18 A. Yes.

19 Q. "This draft brief was
20 reviewed by most of you early last week."

21 Do you agree that the
22 members of the executive committee were
23 given the opportunity to review the
24 brief?

1 MS. CHARLES: Form.

2 THE WITNESS: If it's stated
3 here that they were given an
4 opportunity to review the brief,
5 yes.

6 BY MR. PIFKO:

7 Q. And John Gray further
8 states, "I agree with HDMA counsel that
9 this is the best time to file such a
10 brief, to let the appellate court
11 understand the extent of our industry's
12 concerns and frustrations in trying to
13 work with the DEA on suspicious order
14 monitoring."

15 Did I read that correctly?

16 A. Suspicious ordering
17 monitoring. But, yes.

18 Q. "This may be the last chance
19 to address these issues before an
20 appellate bench in this matter. A
21 favorable decision will establish a
22 useful judicial precedent for all HDMA
23 members to rely upon if necessary."

24 Do you see that?

1 A. Yes.

2 Q. Did you have an
3 understanding about what the significance
4 of the rulings were in this case?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: I understood
8 the process that kind of launched
9 the -- the need for filing of the
10 amicus, yes.

11 BY MR. PIFKO:

12 Q. And what -- what was that?

13 A. Just the process that DEA
14 utilized to issue their suspension order,
15 was what I think we -- we were concerned
16 was vague and, you know, I think
17 illustrated the concerns that the -- the
18 entire industry had with the lack of
19 clarity that the industry had with regard
20 to DEA expectations and their enforcement
21 authorities.

22 Q. Do you know what the outcome
23 of the matter was?

24 MR. WEINSTEIN: Objection to

1 scope.

2 THE WITNESS: In the
3 Cardinal v. Holder case?

4 BY MR. PIFKO:

5 Q. Yeah.

6 A. I don't recall initially.

7 Q. Are you aware that Cardinal
8 Health eventually admitted wrongdoing?

9 MS. WICHT: Objection to
10 form.

11 MR. WEINSTEIN: Objection to
12 scope.

13 THE WITNESS: Again, I --
14 there was resolution of the case.
15 I don't know what the exact
16 details of the resolution were.

17 BY MR. PIFKO:

18 Q. Did anyone tell you that
19 Cardinal Health had admitted wrongdoing?

20 A. I think --

21 MR. WEINSTEIN: Objection to
22 scope.

23 MS. WICHT: Objection to
24 form.

1 THE WITNESS: Again, I think
2 at the time I probably was aware
3 that that was the resolution of
4 the case.

5 BY MR. PIFKO:

6 Q. Okay.

7 (Document marked for
8 identification as Exhibit
9 HDA-Kelly-47.)

10 BY MR. PIFKO:

11 Q. I'm handing you what's
12 marked as Exhibit 47.

13 For the record, Exhibit 47
14 is an e-mail from John Gray dated
15 November 19th, 2015. The subject is
16 "Masters suit, draft amicus outline - for
17 your consideration." It's Bates-labeled
18 HDA_MDL_000219211 through 219213.

19 Take a moment to review it.
20 And let me know when you're done.

21 A. Okay.

22 Q. In Exhibit 47, John Gray is
23 sharing an outline of a draft amicus
24 brief or a draft amicus outline for the

1 Masters Pharmaceutical case with the
2 executive committee, correct?

3 A. Yes.

4 Q. And it's drafted by HDA's
5 inhouse counsel, Ms. Gallenagh?

6 MR. WEINSTEIN: Objection to
7 form. Foundation.

8 THE WITNESS: Yeah, I don't
9 know if this was done by inhouse
10 counsel or outside OFW.

11 BY MR. PIFKO:

12 Q. Well, it's -- it says --
13 it's got her name on it here. Do I have
14 that correct?

15 A. Her name's on the e-mail.

16 Q. Well, but it says from John
17 Gray and Ms. Gallenagh.

18 A. Right.

19 Q. Do you see that?

20 A. Right, but I don't know who
21 drafted the -- the -- this document. I
22 don't know if that was done by inhouse or
23 outside counsel.

24 Q. Ms. Gallenagh is the same

1 counsel that's here today at the
2 deposition?

3 A. That's correct.

4 Q. So this outline and summary
5 memo was provided to HDA's executive
6 committee -- committee members on
7 November 19, 2015, correct?

8 A. Yes.

9 Q. There was a request that
10 people consider this and provide input on
11 whether to pursue it, correct?

12 A. That's correct.

13 (Document marked for
14 identification as Exhibit
15 HDA-Kelly-48.)

16 BY MR. PIFKO:

17 Q. I'm handing you what's
18 marked as Exhibit 48. Take a minute to
19 review Exhibit 48. For the record,
20 Exhibit 48 is a two-page document
21 Bates-labeled HDA_MDL_000215966 through
22 67.

23 It's dated from
24 January 2016, and the subject is "Action

1 requested - HDMA Masters amicus brief."

2 Let me know when you're
3 ready.

4 A. Okay.

5 Q. So in this document,
6 Exhibit 48, John Gray is again e-mailing
7 the executive committee and asking for
8 their approval to move forward with the
9 drafting of the amicus brief in the
10 Masters case, correct?

11 A. That's correct.

12 Q. And he notes that they're
13 going to hire someone from Latham &
14 Watkins, and they estimate the cost is
15 going to be about \$150,000, correct?

16 A. Yes. That's what this
17 states.

18 Q. Okay. And he says that he
19 recommends the executive committee
20 approve based on the following and
21 provides five bullet points describing
22 why Mr. Gray believes that the members
23 should approve the proceeding with
24 drafting and ultimately filing the brief,

1 correct?

2 A. Yes.

3 Q. And we see here on top of
4 the e-mail that AmerisourceBergen
5 approved that course of action, correct?

6 A. Yes.

7 Q. Do you know if the other
8 members approved the filing of the brief?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: I don't know.
12 I know -- I think that the brief
13 was filed, so I'd imagine that
14 they did approve the filing of the
15 brief.

16 BY MR. PIFKO:

17 Q. Again, because they wouldn't
18 file a brief without approval of the
19 executive committee members, correct?

20 A. That's correct.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-49.)

24 BY MR. PIFKO:

1 Q. I'm handing you what's
2 marked as Exhibit 49. Exhibit 49 is a
3 document Bates-labeled HDA_MDL_000162206
4 through 162256. It's an e-mail from you
5 dated April 5, 2016, to Ruth Miller.
6 Subject is "Amicus brief filed in Masters
7 case." It attaches the brief and a
8 consent motion. Let me know when you're
9 done.

10 A. I agree that's what it
11 includes.

12 Q. Okay. That's -- so you say
13 here on the first -- well, first -- this
14 is the final version of the brief that
15 was filed, correct?

16 A. To the best of my knowledge,
17 yes.

18 Q. And you're sharing this with
19 Ruth Miller?

20 A. Yes.

21 Q. Who is that?

22 A. Ruth Miller at the time was
23 in our regulatory affairs department. I
24 believe she was a senior director.

1 Q. And what was her role in the
2 regulatory affairs department?

3 A. Her role was primarily in
4 the DEA-related regulatory affairs
5 issues.

6 Q. What specifically does she
7 do?

8 A. She would basically review
9 various regulatory documents and
10 interactions with the DEA.

11 Q. For what purpose?

12 MR. WEINSTEIN: Objection to
13 form.

14 THE WITNESS: To represent
15 HDA's interest in front of the
16 agency.

17 BY MR. PIFKO:

18 Q. You say here, "Long story
19 short, our members felt it was an
20 important opportunity to weigh in as
21 dispassionately as possible with the
22 Court on some of the ambiguities that
23 Masters referenced in their pleadings as
24 well as some of the points that the

1 administrative law judge addressed in her
2 recommendations to overturn the
3 suspension order."

4 Do you see that?

5 A. I do.

6 Q. Were you part of discussions
7 with the members about this brief?

8 MR. WEINSTEIN: Objection to
9 form.

10 THE WITNESS: Not the
11 details of the brief itself. That
12 was handled by Latham & Watkins.
13 But I was aware that the brief was
14 being crafted and was going to be
15 submitted.

16 BY MR. PIFKO:

17 Q. And the members shared their
18 views on the strategy with you, such that
19 you could provide it here to Ms. Miller?

20 MR. WEINSTEIN: Objection to
21 form. Foundation. Scope.

22 THE WITNESS: The members of
23 this instance would have probably
24 been involved to the legal

1 committee, HDA's legal committee
2 and handled there. So I think
3 they probably did provide feedback
4 to the strategy as it was moving
5 forward.

6 BY MR. PIFKO:

7 Q. What's your understanding of
8 what the ambiguities were that Masters
9 referenced in their pleadings?

10 MR. WEINSTEIN: Objection to
11 form. Scope. Foundation. And
12 calls for a legal conclusion.

13 THE WITNESS: Again, I think
14 some of the ambiguities had to do
15 with the authority that DEA
16 referenced in their action against
17 Masters.

18 (Document marked for
19 identification as Exhibit
20 HDA-Kelly-50.)

21 BY MR. PIFKO:

22 Q. I'm handing you what's
23 marked Exhibit 50. For the record,
24 Exhibit 50 is an e-mail attaching another

1 amicus brief that was filed in the West
2 Virginia Supreme Court of Appeals. It's
3 Bates-labeled HDA_MDL_000212579 through
4 212616.

5 A. Okay.

6 Q. Are you aware that HDMA
7 filed an amicus brief in the West
8 Virginia State Court litigation against
9 the distributors?

10 A. I am.

11 Q. And did the executive
12 committee authorize the filing of that
13 brief?

14 A. I would think that they
15 would have, yes.

16 Q. Do you have any reason to
17 believe that they wouldn't have supported
18 it?

19 A. No.

20 MS. WICHT: Objection to
21 form.

22 BY MR. PIFKO:

23 Q. I'm going to turn your
24 attention back to Exhibit 1, the subpoena

1 with the topics. Are you there?

2 A. I am.

3 Q. Okay. Topic Number 3 is
4 your lobbying activities related to the
5 manufacture, marketing, advertising and
6 distribution of opioids or opioid
7 products.

8 Do you see that?

9 A. I do.

10 Q. Do you understand yourself
11 to be -- have been designated to talk
12 about that topic here today?

13 A. I do.

14 Q. We talked about Topic 4
15 already.

16 Topic Number 5: Your
17 advocacy or legal support for any
18 defendant, including but not limited to,
19 amicus curiae briefs or any -- or other
20 legal documents prepared by you in
21 support of any defendant.

22 Do you see that?

23 A. I do.

24 Q. Do you understand yourself

1 to be designated to talk on that topic
2 today?

3 A. I do.

4 Q. Topic Number 6: The nature,
5 scope and identity of any conferences,
6 seminars or webinars you have sponsored,
7 promoted or organized where the duty to
8 prevent diversion and identify and report
9 suspicious orders was included among the
10 topics of discussion.

11 Do you see that?

12 A. I do.

13 Q. Do you understand yourself
14 to be designated to talk on that topic
15 today?

16 A. I do.

17 Q. Topic Number 7:
18 Communications with the DEA or any state
19 or federal government agency regarding
20 the diversion or suspicious orders of
21 opioids or opioid products, including but
22 not limited to, the attendance,
23 participation in, presentations given by
24 the DEA at your conferences, seminars, or

1 webinars regarding advice, direction,
2 guidance or instruction regarding the
3 duty to prevent diversion and identify
4 and report suspicious orders.

5 Do you understand yourself
6 to be designated to talk on that topic
7 today?

8 A. I do.

9 Q. Topic Number 8: Any
10 communications efforts, activities,
11 initiatives or work performed by you
12 regarding quotas set by the DEA,
13 including increases to or maintenance of
14 the quotas.

15 Do you understand yourself
16 to be designated to talk on that topic
17 today?

18 A. Yes.

19 Q. The scope -- Topic
20 Number 12: The scope and nature of any
21 discussions of any council, committee,
22 task force or working group of the HDA
23 concerning opioids.

24 Do you see that?

1 A. I do.

2 Q. Do you understand yourself
3 to be designated to talk on that topic
4 today?

5 A. I do.

6 Q. Topic Number 13: The scope
7 and nature of any discussions of any
8 council, committee, task force, or
9 working group of the HDA concerning
10 diversion of controlled substances.

11 Do you see that?

12 A. I do.

13 Q. Do you understand yourself
14 to be designated to talk on that topic
15 today?

16 A. I do.

17 Q. What did you do to prepare
18 to testify on those topics?

19 A. I met with counsel several
20 days in the last couple days and then
21 previously when we thought this was going
22 to be scheduled earlier, or later in
23 2018. So probably four or five meetings
24 with counsel and staff.

1 Q. Okay. I was going to ask
2 you. Besides counsel, did you meet with
3 any staff members?

4 A. I did. I met with Anita
5 Ducca primarily to understand the period
6 of time I was not at HDA.

7 Q. And did she provide any
8 documents to you?

9 A. Other than the documents
10 that were produced.

11 Q. So she provided documents to
12 you that were produced?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: No. Counsel
16 provided the documents.

17 BY MR. PIFKO:

18 Q. Okay. So when you
19 understood you were going to be
20 designated to come speak for the HDA at
21 this deposition, counsel provided you
22 with documents that had been produced in
23 the litigation?

24 A. That's correct.

1 Q. Okay. And when you met with
2 Ms. Ducca, did we go over any of those
3 documents?

4 A. We did.

5 Q. Okay. Did you review the
6 documents on your own time without
7 anybody?

8 A. I did not.

9 Q. Okay. Who else besides
10 Ms. Ducca from the staff did you meet
11 with?

12 A. Our general counsel
13 participated in the meetings as well.

14 Q. Okay. Anyone else?

15 A. No.

16 Q. About how many hours did you
17 meet with Ms. Ducca?

18 A. Over the course, probably
19 eight -- between eight and ten hours.

20 Q. And you felt, based on those
21 discussions and the review of documents,
22 that you had adequate understanding to
23 testify on those topics I just read to
24 you?

1 A. I do.

2 MR. PIFKO: Okay. We'll
3 take a break.

4 THE VIDEOGRAPHER: The time
5 is 5:09 p.m. We are off the
6 record.

7 (Short break.)

8 THE VIDEOGRAPHER: The time
9 is 5:25 p.m. We are back on the
10 record.

11 (Document marked for
12 identification as Exhibit
13 HDA-Kelly-51.)

14 BY MR. PIFKO:

15 Q. Handing you what's marked as
16 Exhibit 51.

17 And while you are looking --
18 go ahead and take your time to look at
19 that, but then I also want you to pull
20 out Exhibit 11 which goes with
21 Exhibit 51.

22 For the record, Exhibit 51
23 is a three-page document Bates-labeled
24 CAH_MDL2804_02201918 through 1920.

1 A. 11?

2 Q. Yeah.

3 A. Document 11?

4 Q. Okay. You ready?

5 A. Yes.

6 Q. So you recall, when I showed
7 you Document 11 and I asked you if you
8 had an understanding about the date of
9 when the National Wholesale Druggists'
10 Association suspicious order monitoring
11 system, which is Exhibit 11, what the
12 date of that document was, do you recall
13 that discussion?

14 A. I recall that discussion,
15 yes.

16 Q. Okay. Well, Exhibit 51 is a
17 series of letters from the DEA concerning
18 the National Wholesale Druggists'
19 Association's suspicious order monitoring
20 system. And if you see, the first page
21 of Exhibit 51 is stamped April 27, 1984.

22 Do you see that?

23 A. I do.

24 Q. Does that refresh your

1 recollection that Exhibit 11 is from
2 approximately in the early '80s?

3 MR. WEINSTEIN: Objection to
4 form, foundation, scope.

5 THE WITNESS: I will --
6 again, I have not seen either of
7 these documents. I will take it
8 at face value that that was when
9 this document was prepared.

10 BY MR. PIFKO:

11 Q. Okay. Well, Exhibit 51 is a
12 letter from Thomas Gitchel, acting chief
13 diversion operations section of the DEA,
14 correct?

15 A. Yes.

16 Q. And it's dated April 27,
17 1984, correct?

18 A. Yes.

19 Q. And it's to Ronald J.
20 Streck, vice president of government
21 affairs, National Wholesale Druggists'
22 Association.

23 That's a predecessor entity
24 of HDA, correct?

1 A. That's correct.

2 Q. Do you know who Mr. Streck
3 is?

4 A. Mr. Streck became at one
5 point the CEO of the NWDA.

6 Q. Okay. Do you know around
7 the time that was?

8 A. I do not know when he --
9 Mr. Gray did succeed him as the CEO.

10 Q. Okay. Mr. Gray was
11 immediately after him?

12 A. Immediately after him, yes.

13 Q. Okay. So this document
14 says, the second full paragraph, "The
15 NWDA's draft format for suspicious order
16 monitoring system provides an excellent
17 framework for distributor" --
18 "distributor registrants to design and
19 operate a system to disclose to
20 registrants suspicious orders of
21 controlled substances."

22 Do you see that?

23 A. I do.

24 Q. And it says, "Draft format

1 for a suspicious order monitoring
2 system." And Exhibit 11 says,
3 "Suspicious order monitoring system,"
4 correct?

5 A. It does.

6 Q. Okay. Then on the bottom of
7 that same paragraph, Mr. Gitchel says in
8 the letter to Mr. Streck, "As previously
9 discussed, an after-the-fact computer
10 printout of sales data does not relieve a
11 registrant of its responsibility to
12 report excessive or suspicious orders
13 when discovered."

14 Do you see that?

15 A. I do.

16 Q. And then he says, "I'm
17 enclosing a copy of your draft with my
18 pen and ink changes."

19 Do you see that?

20 A. I do.

21 Q. Do you agree -- any reason
22 to dispute that the NWDA received this
23 document?

24 MR. WEINSTEIN: Objection to

1 form. Foundation. Scope.

2 THE WITNESS: No reason to
3 dispute that they received a pen
4 and ink draft marked-up version.

5 BY MR. PIFKO:

6 Q. And this letter from DEA,
7 correct?

8 MR. WEINSTEIN: Same
9 objections.

10 THE WITNESS: No reason to
11 dispute that.

12 BY MR. PIFKO:

13 Q. Based on your understanding
14 of the HDA and as a designee under Rule
15 30(b)(6), do you believe this would have
16 been provided to HDA's members?

17 MR. WEINSTEIN: Objection to
18 form, foundation, and scope.

19 THE WITNESS: Again, I don't
20 know what capabilities were back
21 in 1984. I would imagine it was
22 reported at some point to HDA
23 members.

24 BY MR. PIFKO:

1 Q. Okay. In the first
2 paragraph --

3 A. Or NWDA members.

4 Q. In the first paragraph he
5 says, "I want to thank" -- "I want to
6 take this opportunity to thank you,
7 Mr. Streck, and then Mr. David Prins,
8 from Twin City Wholesale, and Mr. Robert
9 Bone from Bergen Brunswig for meeting
10 with David Walkup and me on April 13,
11 1984."

12 Do you see that?

13 A. I do.

14 Q. So based on this, it appears
15 some of the members in addition to
16 Mr. Streck met with the DEA about the
17 suspicious order monitoring system,
18 correct?

19 A. It would appear so, yes.

20 Q. Then the third page of
21 Exhibit 51 is another letter to
22 Mr. Streck from Thomas Gitchel.

23 Do you see that?

24 A. I do.

1 Q. And it appears to be dated
2 May 16, 1984.

3 Do you see that?

4 A. I do.

5 Q. In the letter from
6 Mr. Gitchel, he says at the bottom of the
7 first full paragraph, "However, I want to
8 make it clear that the submission of
9 monthly printout of after-the-fact sales
10 will not relieve a registrant from the
11 responsibility of reporting excessive or
12 suspicious orders. DEA has interpreted
13 orders to mean prior to shipment."

14 Do you see that?

15 A. I do.

16 Q. And that's consistent with
17 the language that we discussed on Page
18 seven of Exhibit 11 where it says, "DEA
19 has interpreted orders to mean prior to
20 shipment."

21 Do you see that?

22 A. I do.

23 Q. Do you agree that it's --
24 this DEA letter from 1984 is consistent

1 with that language in the NWDA's
2 suspicious order monitoring system?

3 MR. WEINSTEIN: Objection to
4 form, foundation, and scope.

5 THE WITNESS: It appears to
6 be the same statement, yes.

7 BY MR. PIFKO:

8 Q. Do you believe that this May
9 16th, 1984 letter would have been shared
10 with the NWDA's members?

11 MR. WEINSTEIN: Objection to
12 form, foundation, and scope.

13 THE WITNESS: Again, I can't
14 say for certain. I would imagine
15 that it was. As correspondence
16 like this would technically be
17 shared with the membership.

18 BY MR. PIFKO:

19 Q. And again, because HDA and
20 its predecessor entities would act on
21 behalf of the members, not for its own
22 interest, correct?

23 MR. WEINSTEIN: Objection to
24 form, foundation, and scope.

1 THE WITNESS: Most -- yes,
2 as most trade associations do, on
3 behalf of their members.

4 MR. PIFKO: Okay. We're
5 going to hold the deposition of
6 HDA open, given some of the
7 prior -- the deposition of Mr. Fri
8 and some issues we can meet and
9 confer about. We don't have to
10 waste everyone's time.

11 I'm going to turn it over to
12 the Tennessee counsel.

13 MR. WEINSTEIN: We can speak
14 outside. I had no notice, and I
15 do not agree that Tennessee can
16 ask questions. Not after seven
17 hours.

18 MR. STEWART: It's properly
19 noticed.

20 MR. WEINSTEIN: It was not
21 noticed to me. I'm not having my
22 witness testify after seven hours.

23 THE VIDEOGRAPHER: So we're
24 going to go off the record

1 obviously. The time is 5:34 p.m.
2 We're going off the record.

3 (Short break.)

4 THE VIDEOGRAPHER: The time
5 is 5:35 p.m. We're back on the
6 record.

7 MR. STEWART: I'll let you
8 speak.

9 My understanding is that
10 after we've been sitting here for
11 hours and hours, and obviously the
12 expectation was that, as with the
13 deposition earlier in the week,
14 that we would take our two hours
15 of testimony. I'm being told that
16 you are not going to permit the
17 witness to testify today; is that
18 correct?

19 MR. WEINSTEIN: That's
20 correct, Mike. So let me explain.

21 On Tuesday in the deposition
22 of Mr. Fri, you approached me,
23 identified who you were. That was
24 the first that I had ever heard of

1 anything relating to Tennessee. I
2 had not received any notice of a
3 deposition with respect to
4 Mr. Fri.

5 You then e-mailed it to me
6 on the spot. I said that's --
7 this is the first I'm hearing of
8 it. You said, well, we'd like to
9 ask Mr. Fri an hour's worth of
10 questions, and if you'll agree to
11 that, then in exchange we'll agree
12 not to try to depose him in the
13 Tennessee matter.

14 The plaintiffs' deposition
15 of Mr. Fri had only taken a couple
16 of hours or so, he was already
17 there. I said, under those
18 circumstances I'll agree.

19 I never received any notice
20 for Mr. Kelly to give deposition
21 today in the Tennessee matter. In
22 fact, when I spoke to you on
23 Tuesday, you said, well, we can
24 either ask our questions today or

1 we can ask our questions Friday,
2 whatever you want.

3 So I had no -- nor did I get
4 any notice that you were going to
5 try to ask Mr. Kelly any
6 questions. He's been testifying
7 for seven hours. So I'm not
8 agreeing to have Mr. Kelly
9 testify.

10 We also reserve all rights
11 as we did on Tuesday as to whether
12 Tennessee is entitled to
13 testimony, given my understanding
14 that your investigation relates to
15 manufacturers, which Mr. Kelly and
16 HDA have very limited testimony to
17 give regarding. So that's my
18 position.

19 MR. STEWART: That's fine,
20 but the one area we have a factual
21 disagreement, I'm sure in good
22 faith, is that I think if you look
23 back on our statements to each
24 other, where we articulated our

1 deal on Tuesday, I never offered
2 to do that testimony on Friday,
3 because obviously that was a
4 different witness.

5 Now, I understood today we'd
6 be doing the same thing, whereby
7 in exchange for not bringing this
8 witness for a full deposition
9 under Tennessee law, that we would
10 take two hours of testimony today.

11 We noticed this deposition
12 the exact same way we noticed the
13 other deposition.

14 And obviously, unlike
15 Tuesday, I mean, you had notice
16 that we were coming. We've also
17 been sitting here for eight hours.
18 This is the first time that I've
19 heard of this.

20 So to me, what I would do if
21 I were you is, to allow your
22 witness to go forward and testify.
23 I'm happy to make the same
24 agreement whereby if he'll testify

1 for two hours, we won't bring him
2 back in this litigation.

3 Obviously, if not, I believe
4 this is properly noticed. It's
5 potentially sanctionable to not
6 allow him to testify.

7 Also, we may well simply
8 subpoena him for a Tennessee
9 deposition under Tennessee rules.
10 And if we do so, of course, I want
11 to make sure this is clear, under
12 the Tennessee rules, a deposition
13 has no time and it continues from
14 day-to-day. And we'll just, if we
15 choose to subpoena him, based on
16 this failure today, obviously we
17 won't restrict our time in any
18 way.

19 To me, it would seem to make
20 more sense since we are all
21 sitting here just to go ahead and
22 take the deposition. But
23 obviously I can't force you to
24 produce your witness other than to

1 provide you a notice which we have
2 done.

3 MR. WEINSTEIN: You actually
4 haven't, Mike. I don't have that
5 notice.

6 Did you -- are you telling
7 me that you sent me that notice?
8 Because you have not.

9 MR. STEWART: Well, I can
10 tell you -- I'm speaking obviously
11 for my law firm. I don't handle
12 that notice --

13 MR. WEINSTEIN: Yeah.

14 MR. STEWART: -- but I just
15 spoke to the person who provides
16 the notices, whose noticed at
17 least 45 depositions in the opioid
18 litigation. We've never had a
19 problem like this before today.

20 So I think when I tell you
21 that our firm has properly noticed
22 this, I think it's unlikely that
23 after so many depositions with no
24 hiccoughs and no difficulties,

1 that for some reason this
2 deposition proved to be a problem.

3 MR. WEINSTEIN: Mike, we are
4 a third party. Never received
5 your first notice until you handed
6 it to me by e-mail when we were
7 standing out in the hall on
8 Tuesday. Never received a notice
9 with respect to Mr. Kelly. So
10 we're not changing our position.

11 MR. STEWART: I understand.
12 Well, I think -- I think that
13 problem that puts us -- gives us
14 is that then our choice, I
15 suppose, is to seek sanctions in
16 our litigation.

17 Or, and as an alternative,
18 or as coupled with that, to just
19 subpoena your witness and come
20 back for a deposition.

21 MR. WEINSTEIN: Mike --

22 MR. STEWART: I think the
23 notion that this testimony is not
24 relevant to the Tennessee

1 litigation and to the opioid
2 crisis in Tennessee has been amply
3 disproven by the testimony that's
4 already been taken today.

5 But I don't -- it doesn't
6 sound like we're going to reach an
7 agreement --

8 MR. WEINSTEIN: Correct.

9 MR. STEWART: -- so I've
10 told you what we're planning to
11 do. I've informed you.

12 And it sounds like with that
13 information you're continuing to
14 hold to your position of not
15 allowing us to take questions
16 today; is that correct?

17 MR. WEINSTEIN: That's
18 correct.

19 MR. STEWART: Okay. That's
20 unfortunate. And obviously we'll
21 both just have to take the steps
22 to do what we have to for our
23 clients.

24 MR. WEINSTEIN: That's

1 correct.

2 THE VIDEOGRAPHER: Any other
3 statements on the record? Is that
4 it for today?

5 MS. MACKAY: I have a few
6 questions.

7 MR. WEINSTEIN: Go ahead.

8 - - -

9 EXAMINATION

10 - - -

11 BY MS. MACKAY:

12 Q. My name is Melanie Mackay,
13 I'm from Dechert. I'm one of the
14 attorneys who represents Purdue. I just
15 have a few questions for you. And I'm
16 sorry, they are on my computer, so if I'm
17 looking at my computer screen I'm not
18 ignoring you. I'm just looking at my
19 questions?

20 A. Okay.

21 Q. So Purdue is a manufacturer.
22 And I believe you said earlier that
23 Purdue is an affiliate member; is that
24 correct?

1 A. I believe so, yes.

2 Q. And can you describe what it
3 means to be an affiliate member?

4 A. So affiliate members at HDA
5 are manufacturers who our member
6 companies are trading partners with.
7 They are not afforded the same membership
8 status as the core members who are the
9 distributor members. They are not
10 allowed to participate in committees.
11 They can't be on the board. They are
12 welcome to participate in HDA meetings
13 and external events if they register for
14 those. But as far as communication
15 internal, particularly in government
16 affairs, we deal strictly with the HDA
17 core members.

18 Q. Plaintiff's counsel today
19 often used the term "HDA members." And I
20 just want to clarify how you understand
21 that term.

22 Unless counsel specifically
23 referred to manufacturers, did you
24 understand the term "members" to mean

1 core members?

2 A. Yes. I believe we -- did we
3 not stipulate to that early on? Yes,
4 that's what I'm -- yes, that was my
5 understanding.

6 Q. Okay. And again, the core
7 members are distributors?

8 A. That's correct.

9 Q. You may have already
10 answered this question for me. But are
11 manufacturers members of any committees
12 or other groups that fall under the
13 umbrella of the government affairs
14 department?

15 A. The only -- the only
16 committee within HDA that manufacturers
17 are allowed to participate in is there's
18 a government advisory -- manufacturers
19 government advisory committee that meets
20 twice a year. And that is essentially an
21 opportunity for us to provide an update
22 on HDA government affairs activities.

23 But that does not meet, it
24 does not meet in person. We do not

1 convene interaction. We just do an
2 update twice a year.

3 Q. Did Purdue or any other
4 manufacturer ever serve on the regulatory
5 affairs committee?

6 A. No.

7 Q. And I believe you testified
8 earlier that the -- the regulatory
9 affairs committee created the -- HDA's
10 industry compliance guidelines; is that
11 correct?

12 A. That's -- that's correct.

13 Q. The industry compliance
14 guidelines are guidelines for
15 distributors; is that right?

16 A. That's correct.

17 Q. They are not meant to be
18 implemented by manufacturers?

19 A. That is correct.

20 Q. You briefly testified about
21 the drug diversion DEA strategy task
22 force. Do you recall that?

23 A. I do.

24 Q. Did manufacturer members

1 serve on that task force?

2 A. They did not.

3 Q. Switching gears back to the
4 industry compliance guidelines, did
5 manufacturers participate in the
6 development and drafting of the industry
7 compliance guidelines?

8 A. They did not.

9 Q. Did the Pain Care Forum
10 participate in the development and
11 drafting of the industry compliance
12 guidelines?

13 A. They did not.

14 MS. MACKAY: That's the only
15 questions I have for you. Thank
16 you.

17 MR. WEINSTEIN: I'd like to
18 designate the transcript as
19 confidential, please.

20 THE VIDEOGRAPHER: Anybody
21 else? Okay. Do you want to close
22 the record?

23 The time is 5:45 p.m., May
24 10, 2019. We are going off the

1 record.

2 This ends this videotape
3 session.

4 (Excused.)

5 (Deposition concluded at
6 approximately 5:45 p.m.)

7

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1
2 CERTIFICATE
3
4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, PATRICK KELLY, have the
12 opportunity to read and sign the
13 deposition transcript.

14 
15 MICHELLE L. GRAY,
16 A Registered Professional
17 Reporter, Certified Shorthand
18 Reporter, Certified Realtime
19 Reporter and Notary Public
20 Dated: May 13, 2019
21
22
23
24

25 (The foregoing certification
26 of this transcript does not apply to any
27 reproduction of the same by any means,
28 unless under the direct control and/or
29 supervision of the certifying reporter.)
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34

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

1

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E R R A T A

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1
2 ACKNOWLEDGMENT OF DEPONENT

3
4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 448, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.

13
14
15
16 _____
17 PATRICK KELLY

DATE

18
19
20 Subscribed and sworn
to before me this

21 _____ day of _____, 20____.

22 My commission expires: _____
23 _____

24 Notary Public

1	LAWYER'S NOTES		
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18	_____	_____	_____
19	_____	_____	_____
20	_____	_____	_____
21	_____	_____	_____
22	_____	_____	_____
23	_____	_____	_____
24	_____	_____	_____